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(54) **PROSTHETIC JOINT ASSEMBLY AND  
PROSTHETIC JOINT MEMBER**

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(56) **References Cited**

**U.S. PATENT DOCUMENTS**

3,521,302 A 7/1970 Muller  
3,723,995 A 4/1973 Baumann

(Continued)

**FOREIGN PATENT DOCUMENTS**

DE 4102509 7/1992  
DE 4102510 7/1992

(Continued)

**OTHER PUBLICATIONS**

Alvarado et al. "Biomechanics of Hip and Knee Prostheses". Uni-  
versity of Puerto Rico Mayaguez (2003): 1-20.

(Continued)

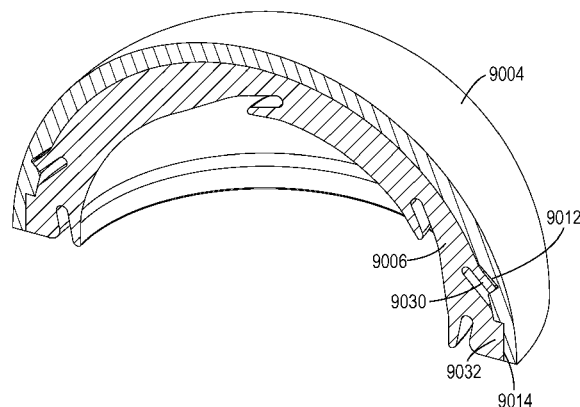
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(57) **ABSTRACT**

A prosthetic joint member includes: a generally concave cup  
with an outer surface that is bone-implantable, the cup includ-  
ing a first indexing feature; a concave insert disposed inside  
the cup, the insert comprising a rigid material and including a  
concave interior defining a nominal surface, the interior  
including a cantilevered flange defined by an undercut in the  
insert, the flange defining a wear-resistant first contact surface  
which protrudes inward relative to the nominal surface, the  
insert including a second indexing feature. The first and sec-  
ond indexing features engage each other so as to retain the  
insert in a fixed angular orientation relative to the cup.

**18 Claims, 48 Drawing Sheets**



**Related U.S. Application Data**

is a continuation of application No. 13/073,963, filed on Mar. 28, 2011, now Pat. No. 8,070,823, which is a continuation-in-part of application No. 12/826,620, filed on Jun. 29, 2010, now Pat. No. 7,914,580, which is a continuation-in-part of application No. 12/714,288, filed on Feb. 26, 2010, now Pat. No. 7,905,919, which is a continuation-in-part of application No. 11/936,601, filed on Nov. 7, 2007, now Pat. No. 9,005,306.

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(56)

**References Cited**

## U.S. PATENT DOCUMENTS

3,744,061 A 10/1973 Frost  
3,842,442 A 10/1974 Kolbel  
3,916,451 A 11/1975 Buechel et al.  
3,945,739 A 3/1976 Abe  
4,031,570 A 6/1977 Frey  
4,044,403 A 8/1977 D'Errico  
4,123,806 A 11/1978 Amstutz et al.  
4,126,924 A 11/1978 Akins et al.  
4,159,544 A 7/1979 Termanini  
4,224,696 A 9/1980 Murray et al.  
4,309,778 A 1/1982 Buechel et al.  
4,437,193 A 3/1984 Oh  
4,550,450 A 11/1985 Kinnett

4,568,348 A 2/1986 Johnson et al.  
4,662,891 A 5/1987 Noiles  
4,673,408 A 6/1987 Grobbelaar  
4,676,798 A 6/1987 Noiles  
4,718,911 A 1/1988 Kenna  
4,759,766 A 7/1988 Buettner Janz et al.  
4,795,469 A 1/1989 Oh  
4,813,961 A 3/1989 Sostegni  
4,878,918 A 11/1989 Tari et al.  
4,904,106 A 2/1990 Love  
4,919,674 A 4/1990 Schelhas  
4,955,919 A 9/1990 Pappas et al.  
4,964,865 A 10/1990 Burkhead et al.  
4,997,432 A 3/1991 Keller  
5,019,105 A 5/1991 Wiley  
5,061,288 A 10/1991 Berggren et al.  
5,062,853 A 11/1991 Forte  
5,080,675 A 1/1992 Lawes et al.  
5,080,678 A 1/1992 Spotorno et al.  
5,092,898 A 3/1992 Bekki et al.  
5,095,898 A 3/1992 Don Michael  
5,116,375 A 5/1992 Hofmann  
5,116,376 A 5/1992 May  
5,133,769 A 7/1992 Wagner et al.  
5,181,926 A 1/1993 Koch et al.  
5,197,987 A 3/1993 Koch et al.  
5,314,477 A 5/1994 Marnay  
5,358,530 A 10/1994 Hodorek  
5,389,107 A 2/1995 Nassar et al.  
5,405,394 A 4/1995 Davidson  
5,413,604 A 5/1995 Hodge  
5,458,650 A 10/1995 Carret et al.  
5,462,362 A 10/1995 Yuhta et al.  
5,480,442 A 1/1996 Bertagnoli  
5,480,446 A 1/1996 Goodfellow et al.  
5,480,448 A 1/1996 Mikhail  
5,507,816 A 4/1996 Bullivant  
5,549,693 A 8/1996 Roux et al.  
5,549,695 A 8/1996 Spotorno et al.  
5,549,697 A 8/1996 Caldarise  
5,549,699 A 8/1996 MacMahon et al.  
5,549,700 A 8/1996 Graham et al.  
5,593,445 A 1/1997 Waits  
5,609,645 A 3/1997 Vinciguerra  
5,641,323 A 6/1997 Caldarise  
5,674,296 A 10/1997 Bryan et al.  
5,676,701 A 10/1997 Yuan et al.  
5,676,704 A 10/1997 Ries et al.  
5,702,456 A 12/1997 Pienkowski  
5,702,470 A 12/1997 Menon  
5,702,478 A 12/1997 Tornier  
5,725,584 A 3/1998 Walker et al.  
5,766,260 A 6/1998 Whiteside  
5,782,927 A 7/1998 Klawitter et al.  
5,800,555 A 9/1998 Gray et al.  
5,824,101 A 10/1998 Pappas  
5,824,107 A 10/1998 Tschirren  
5,871,542 A 2/1999 Goodfellow et al.  
5,871,546 A 2/1999 Colleran et al.  
5,879,404 A 3/1999 Bateman et al.  
5,879,406 A 3/1999 Lilley  
5,879,407 A 3/1999 Waggener  
5,893,889 A 4/1999 Harrington  
5,916,269 A 6/1999 Serbousek et al.  
5,935,174 A 8/1999 Dye  
5,935,175 A 8/1999 Ostiguy, Jr. et al.  
5,938,702 A 8/1999 Lopez et al.  
5,957,979 A 9/1999 Beckman et al.  
5,989,293 A 11/1999 Cook et al.  
5,989,294 A 11/1999 Marlow  
5,997,579 A 12/1999 Albrechtsson et al.  
6,013,103 A 1/2000 Kaufman et al.  
6,042,293 A 3/2000 Maughan  
6,059,830 A 5/2000 Lippencott, III et al.  
6,080,195 A 6/2000 Colleran et al.  
6,096,083 A 8/2000 Keller et al.  
6,126,695 A 10/2000 Semlitsch  
6,129,765 A 10/2000 Lopez et al.  
6,146,421 A 11/2000 Gordon et al.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

6,152,961	A	11/2000	Ostiguy, Jr. et al.	7,468,079	B2	12/2008	Collier
6,162,252	A	12/2000	Kuras et al.	7,470,287	B2	12/2008	Tornier et al.
6,162,256	A	12/2000	Ostiguy, Jr. et al.	7,485,145	B2	2/2009	Purcell
6,179,874	B1	1/2001	Cauthen	7,494,507	B2	2/2009	Dixon et al.
6,190,415	B1	2/2001	Cooke et al.	7,531,002	B2	5/2009	Sutton et al.
6,203,576	B1	3/2001	Afriat et al.	7,537,615	B2	5/2009	Lemaire
6,206,929	B1	3/2001	Ochoa et al.	7,550,009	B2	6/2009	Arnin et al.
6,217,249	B1	4/2001	Merlo	7,550,010	B2	6/2009	Humphreys et al.
6,231,264	B1	5/2001	McLaughlin et al.	7,572,295	B2	8/2009	Steinberg
6,299,646	B1	10/2001	Chambat et al.	7,572,296	B2	8/2009	Scott et al.
6,364,910	B1	4/2002	Shultz et al.	7,578,848	B2	8/2009	Albert et al.
6,368,350	B1	4/2002	Erickson et al.	7,582,115	B2	9/2009	Weber
6,375,682	B1	4/2002	Fleischmann et al.	7,588,384	B2	9/2009	Yokohara
6,416,553	B1	7/2002	White et al.	7,601,174	B2	10/2009	Kelly et al.
6,425,921	B1	7/2002	Grunde et al.	7,611,653	B1	11/2009	Elsner et al.
6,475,243	B1	11/2002	Sheldon et al.	7,618,439	B2	11/2009	Zubok et al.
6,494,916	B1	12/2002	Babalola et al.	7,618,459	B2	11/2009	Justin et al.
6,537,321	B1	3/2003	Horber	7,621,956	B2	11/2009	Paul et al.
6,558,427	B2	5/2003	Leclercq et al.	7,655,041	B2	2/2010	Clifford et al.
6,626,947	B2	9/2003	Lester et al.	7,658,767	B2	2/2010	Wys
6,660,040	B2	12/2003	Chan et al.	7,682,398	B2	3/2010	Croxton et al.
RE38,409	E	1/2004	Noiles	7,740,659	B2	6/2010	Zarda et al.
6,719,800	B2	4/2004	Meyers et al.	7,758,645	B2	7/2010	Studer
6,740,117	B2	5/2004	Ralph et al.	7,758,653	B2	7/2010	Steinberg
6,740,118	B2	5/2004	Eisermann et al.	7,776,085	B2	8/2010	Bernero et al.
6,743,258	B1	6/2004	Keller	7,879,095	B2	2/2011	Pisharodi
6,770,095	B2	8/2004	Grinberg et al.	7,905,919	B2	3/2011	Kellar et al.
6,866,685	B2	3/2005	Chan et al.	7,914,580	B2	3/2011	Kellar et al.
6,875,235	B2	4/2005	Ferree	7,955,395	B2	6/2011	Shea et al.
6,893,465	B2	5/2005	Huang	8,007,539	B2	8/2011	Slone
6,896,703	B2	5/2005	Barbieri et al.	8,029,574	B2	10/2011	Kellar et al.
6,916,342	B2	7/2005	Frederick et al.	8,070,823	B2	12/2011	Kellar et al.
6,942,701	B2	9/2005	Taylor	8,308,812	B2	11/2012	Kellar et al.
6,949,105	B2	9/2005	Bryan et al.	2002/0035400	A1	3/2002	Bryan et al.
6,964,686	B2	11/2005	Gordon	2002/0111682	A1	8/2002	Ralph et al.
6,972,039	B2	12/2005	Metzger et al.	2002/0143402	A1	10/2002	Steinberg
6,981,989	B1	1/2006	Fleischmann et al.	2002/0147499	A1	10/2002	Shea et al.
6,981,991	B2	1/2006	Ferree	2003/0055500	A1	3/2003	Fell et al.
6,986,791	B1	1/2006	Metzger	2003/0081989	A1	5/2003	Kondoh
7,001,433	B2	2/2006	Songer et al.	2003/0114935	A1	6/2003	Chan et al.
7,022,142	B2	4/2006	Johnson	2003/0191534	A1	10/2003	Viat et al.
7,025,787	B2	4/2006	Bryan et al.	2003/0220691	A1	11/2003	Songer et al.
7,037,341	B2	5/2006	Nowakowski	2004/0010316	A1	1/2004	William et al.
7,060,099	B2	6/2006	Carli et al.	2004/0024460	A1	2/2004	Ferree
7,060,101	B2	6/2006	O'Connor et al.	2004/0034433	A1	2/2004	Chan et al.
7,066,963	B2	6/2006	Naegerl	2004/0073311	A1	4/2004	Ferree
7,083,650	B2	8/2006	Moskowitz et al.	2004/0088052	A1	5/2004	Dearnaley
7,083,651	B2	8/2006	Diaz et al.	2004/0093087	A1	5/2004	Ferree et al.
7,083,652	B2	8/2006	McCue et al.	2004/0117021	A1	6/2004	Biedermann et al.
7,108,719	B2	9/2006	Horber	2004/0143332	A1	7/2004	Krueger et al.
7,108,720	B2	9/2006	Hanes	2004/0143334	A1	7/2004	Ferree
7,115,145	B2	10/2006	Richards	2004/0167626	A1	8/2004	Geremakis et al.
7,121,755	B2	10/2006	Schlapfer et al.	2004/0167629	A1	8/2004	Geremakis et al.
7,128,761	B2	10/2006	Kuras et al.	2004/0172021	A1	9/2004	Khalili
7,153,325	B2	12/2006	Kim et al.	2004/0215345	A1	10/2004	Perrone, Jr. et al.
7,153,328	B2	12/2006	Kim	2004/0220674	A1	11/2004	Pria et al.
7,160,332	B2	1/2007	Frederick et al.	2004/0260396	A1	12/2004	Ferree et al.
7,179,294	B2	2/2007	Eisermann et al.	2004/0267374	A1	12/2004	Friedrichs
7,214,243	B2	5/2007	Taylor	2004/0267375	A1	12/2004	Friedrichs
7,214,244	B2	5/2007	Zubok et al.	2005/0004572	A1	1/2005	Biedermann et al.
7,250,060	B2	7/2007	Trieu	2005/0015152	A1	1/2005	Sweeney
7,267,693	B1	9/2007	Mandell et al.	2005/0021145	A1	1/2005	de Villiers et al.
7,270,679	B2	9/2007	Istephanous et al.	2005/0038516	A1	2/2005	Spoonamore
7,276,082	B2	10/2007	Zdeblick et al.	2005/0055101	A1	3/2005	Sifneos
7,297,164	B2	11/2007	Johnson et al.	2005/0071007	A1	3/2005	Malek
7,309,363	B2	12/2007	Dietz	2005/0080488	A1	4/2005	Schultz
7,326,250	B2	2/2008	Beaurain et al.	2005/0113926	A1	5/2005	Zucherman et al.
7,326,252	B2	2/2008	Otto et al.	2005/0113931	A1	5/2005	Horber
7,326,253	B2	2/2008	Synder et al.	2005/0125065	A1	6/2005	Zucherman et al.
7,338,529	B1	3/2008	Higgins	2005/0143827	A1	6/2005	Globerman et al.
7,393,362	B2	7/2008	Cruchet et al.	2005/0165485	A1	7/2005	Trieu
7,407,513	B2	8/2008	Alleyne et al.	2005/0171604	A1	8/2005	Michalow
7,442,211	B2	10/2008	de Villiers et al.	2005/0171614	A1	8/2005	Bacon
7,465,320	B1	12/2008	Kito et al.	2005/0192674	A1	9/2005	Ferree
7,468,076	B2	12/2008	Zubok et al.	2005/0197706	A1	9/2005	Hovorka et al.
				2005/0203626	A1	9/2005	Sears et al.
				2005/0216081	A1	9/2005	Taylor
				2005/0251261	A1	11/2005	Peterman
				2005/0251262	A1	11/2005	de Villiers et al.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

2005/0261776	A1	11/2005	Taylor	2009/0082867	A1	3/2009	Sebastian Bueno et al.
2005/0288793	A1	12/2005	Dong et al.	2009/0082873	A1	3/2009	Hazebrouck et al.
2006/0020342	A1	1/2006	Ferree et al.	2009/0088865	A1	4/2009	Brehm
2006/0025862	A1	2/2006	Villiers et al.	2009/0105758	A1	4/2009	Gimbel et al.
2006/0041314	A1	2/2006	Millard	2009/0125111	A1	5/2009	Copf, Jr.
2006/0064169	A1	3/2006	Ferree	2009/0138090	A1	5/2009	Hurlbert et al.
2006/0085076	A1	4/2006	Krishna et al.	2009/0157185	A1	6/2009	Kim
2006/0095135	A1	5/2006	Kovacevic	2009/0192616	A1	7/2009	Zielinski
2006/0129240	A1	6/2006	Lessar et al.	2009/0192617	A1	7/2009	Arramon et al.
2006/0136062	A1	6/2006	DiNello et al.	2009/0215111	A1	8/2009	Veenstra et al.
2006/0178744	A1	8/2006	de Villiers et al.	2009/0222089	A1	9/2009	Hauri et al.
2006/0190079	A1	8/2006	Istephanous et al.	2009/0234458	A1	9/2009	de Villiers et al.
2006/0200247	A1	9/2006	Charrois	2009/0248161	A1	10/2009	Theofilos et al.
2006/0217809	A1	9/2006	Albert et al.	2009/0265009	A1	10/2009	Ward et al.
2006/0217815	A1	9/2006	Gibbs et al.	2009/0270986	A1	10/2009	Christensen
2006/0235527	A1	10/2006	Buettner-Janz et al.	2009/0276051	A1	11/2009	Arramon et al.
2006/0241765	A1	10/2006	Burn et al.	2009/0281629	A1	11/2009	Roebeling et al.
2006/0241766	A1	10/2006	Felton et al.	2009/0306784	A1	12/2009	Blum
2006/0259147	A1	11/2006	Krishna et al.	2009/0306785	A1	12/2009	Farrar et al.
2006/0259148	A1	11/2006	Bar-Ziv	2009/0326656	A1	12/2009	de Villiers et al.
2006/0271200	A1	11/2006	Greenlee	2009/0326663	A1	12/2009	Dun
2006/0293752	A1	12/2006	Moumene et al.	2009/0326664	A1	12/2009	Wagner et al.
2007/0021837	A1	1/2007	Ashman	2009/0326665	A1	12/2009	Wyss et al.
2007/0032875	A1	2/2007	Blacklock et al.	2009/0326666	A1	12/2009	Wyss et al.
2007/0032877	A1	2/2007	Whiteside	2009/0326668	A1	12/2009	Dun
2007/0050032	A1	3/2007	Gittings et al.	2010/0004746	A1	1/2010	Arramon
2007/0073405	A1	3/2007	Verhulst et al.	2010/0030335	A1	2/2010	Arramon
2007/0073410	A1	3/2007	Raugel	2010/0063589	A1	3/2010	Tepic
2007/0083267	A1	4/2007	Miz et al.	2010/0063597	A1	3/2010	Gradel
2007/0100447	A1	5/2007	Steinberg	2010/0100189	A1	4/2010	Metzger
2007/0100454	A1	5/2007	Burgess et al.	2010/0100191	A1	4/2010	May et al.
2007/0100456	A1	5/2007	Dooris et al.	2010/0131073	A1	5/2010	Meridew et al.
2007/0106391	A1	5/2007	Ronk	2010/0161064	A1	6/2010	Kellar et al.
2007/0118223	A1	5/2007	Allard et al.	2010/0161072	A1	6/2010	Drescher
2007/0123990	A1	5/2007	Sharifi-Mehr	2010/0191342	A1	7/2010	Byrd et al.
2007/0156246	A1	7/2007	Meswania et al.	2010/0262250	A1	10/2010	Kellar et al.
2007/0168037	A1	7/2007	Posnick	2010/0268340	A1	10/2010	Capote et al.
2007/0173936	A1	7/2007	Hester et al.	2010/0292794	A1	11/2010	Metz-Stavenhagen
2007/0185578	A1	8/2007	O'Neil et al.	2010/0331993	A1	12/2010	Gradl
2007/0208427	A1	9/2007	Davidson et al.	2011/0009975	A1	1/2011	Allen et al.
2007/0213821	A1	9/2007	Kwak et al.	2011/0015752	A1	1/2011	Meridew
2007/0219638	A1	9/2007	Jones et al.	2011/0087333	A1	4/2011	Kellar et al.
2007/0225806	A1	9/2007	Squires et al.	2011/0166671	A1	7/2011	Kellar et al.
2007/0225810	A1	9/2007	Colleran et al.	2011/0190901	A1	8/2011	Weissberg et al.
2007/0225818	A1	9/2007	Reubelt et al.	2011/0276146	A1	11/2011	Segal et al.
2007/0233244	A1	10/2007	Lopez et al.	2012/0083896	A1	4/2012	Kellar et al.
2007/0239276	A1	10/2007	Squires et al.	2012/0265318	A1	10/2012	Forsell
2008/0065211	A1	3/2008	Albert et al.				
2008/0065216	A1	3/2008	Hurlbert et al.				
2008/0071381	A1	3/2008	Buscher et al.				
2008/0077137	A1	3/2008	Balderston				
2008/0133017	A1	6/2008	Beyar et al.				
2008/0133022	A1	6/2008	Caylor				
2008/0154263	A1	6/2008	Janowski et al.				
2008/0154369	A1	6/2008	Barr et al.				
2008/0161924	A1	7/2008	Viker				
2008/0161930	A1	7/2008	Carls et al.				
2008/0195212	A1	8/2008	Nguyen et al.				
2008/0215156	A1	9/2008	Duggal et al.				
2008/0221689	A1	9/2008	Chaput et al.				
2008/0221690	A1	9/2008	Chaput et al.				
2008/0228276	A1	9/2008	Mathews et al.				
2008/0228282	A1	9/2008	Brodowski				
2008/0243253	A1	10/2008	Levieux				
2008/0243262	A1	10/2008	Lee				
2008/0243263	A1	10/2008	Lee et al.				
2008/0300685	A1	12/2008	Carls et al.				
2009/0005872	A1	1/2009	Moumene et al.				
2009/0012619	A1	1/2009	Cordaro et al.				
2009/0030521	A1	1/2009	Lee et al.				
2009/0036992	A1	2/2009	Tsakonas				
2009/0043391	A1	2/2009	de Villiers et al.				
2009/0054986	A1	2/2009	Cordaro et al.				
2009/0062920	A1	3/2009	Tauber				
2009/0076614	A1	3/2009	Arramon				

## FOREIGN PATENT DOCUMENTS

DE	4423020	1/1996
DE	10164328	7/2003
DE	202008004709	7/2008
EP	46926	3/1982
EP	636353	2/1995
EP	648478	4/1995
EP	974316	1/2000
EP	1114624	7/2001
EP	1508315	2/2005
EP	2158879	3/2010
FR	2750036	12/1997
FR	2805456	8/2001
FR	2883723	10/2006
FR	2897528	8/2007
FR	2936145	3/2010
GB	1322680	7/1973
GB	1417407	12/1975
GB	1527498	10/1978
GB	1528906	10/1978
GB	2191402	12/1987
JP	2004011782	1/2004
JP	2004169820	6/2004
RU	2121319	11/1998
WO	9523566	9/1995
WO	9604867	2/1996
WO	9716138	5/1997
WO	9738650	10/1997
WO	0023015	4/2000
WO	03049649	6/2003

(56)

**References Cited**

## FOREIGN PATENT DOCUMENTS

WO	2004066882	8/2004
WO	2005039455	5/2005
WO	2006069465	7/2006
WO	2007087730	8/2007
WO	2008088777	7/2008
WO	2008094260	8/2008
WO	2009094477	7/2009
WO	2009105884	9/2009
WO	2009121450	10/2009
WO	2009126908	10/2009
WO	2010095125	8/2010
WO	2011011340	1/2011

## OTHER PUBLICATIONS

Wang, W., Wang, F., Jin, Z., Dowson, D., Hu, Y., "Numerical Lubrication Simulation of Metal-on-Metal Artificial 1 Hip Joint Replacements: Ball-in-Socket Model and Ball-on-Plane Model", vol. 223 Part J, 2009, pp. 1073-1082, *Journal Engineering Tribology*, [online] [retrieved Mar. 28, 2011].

Wang, F., Jin, Z., "Effect of Non-Spherical Bearing Geometry on Transient Elastohydrodynamic Lubrication in Metal-on-Metal Hip Joint Replacements", vol. 221, Part J, 2007, pp. 379-389, "Journal of Engineering Tribology", [online] D [retrieved Mar. 28, 2011].

Wang, F., Brockett, C., Williams, S., Udofia, I., Fisher, J., Jin, Z., "Lubrication and Friction Prediction in Metal-on-Metal Hip Implants", vol. 53, Jan. 2008, pp. 1277-1293, "Phys. Med. Biol.", United Kingdom, D.

Clarke, I., "Role of Ceramic Implants: Design and Clinical Success with Total Hip Prosthetic Ceramic-to-Ceramic Bearings", No. 282, Sep. 1992, pp. 19-30, "Clinical Orthopaedics and Related Research", Kinamed, Inc., Newbury Park, California.

Gardelin, P., Seminario, J., Corradini, C., Fenollosa Gomez, J., "Total Hip Prostheses with Cup and Ball in Ceramic and Metal Sockets", vols. 192-195, 2001, pp. 983-988, "Key Engineering Materials", Trans Tech Publications, Switzerland.

Bruckmann, H., Keuscher, G., Hutter, K., "Carbon, A Promising Material in Endoprosthetics. Part 2: Tribological Properties", vol. 1, Apr. 1980, pp. 73-81, "Biomaterials", IPC Business Press, West Germany, D.

Jalali-Vahid, D., Jagatia, M., Jin, Z., Dowson, D., "Prediction of Lubricating Film Thickness in UHMWPE Hip Joint Replacements", vol. 34, 2001, pp. 261-266, "Journal of Biomechanics", Elsevier Science Ltd., United Kingdom.

Minns, R.J., Campbell, J., "The 'Sliding Meniscus' Knee Prosthesis: Design Concepts", vol. 8, No. 4, Oct. 1979, pp. 201-205, "Engineering in Medicine", London, England.

Swanson, S., "The State of the Art in Joint Replacement, Part 2: Present Practice and Results", pp. 335-339, Nov. 1977, "Journal of Medical Engineering and Technology", London, United Kingdom.

Faizan, Ahmad, Goei, Vijay K., Garfin, Steven R., Bono, Christopher M., Serhan, Hassan, Biyani, Ashok, Eigafy, Hossein, Krishna, Manoj, Friesem, Tai, "Do Design Variations in the Artificial Disc Influence Cervical Spine Biomechanics? A Finite Element Investigation", Engineering Center for Orthopaedic Research Excellence (E-O CORE), Departments of Bioengineering and Orthopaedic Surgery, 5046 NI, MS 303, Colleges of Engineering and Medicine, University of Toledo, Toledo, Ohio 43606, USA, Published online: Nov. 21, 2009.

Post, Zachary D., Matar, Wadih Y., Van De Leur, Tim, Grossman, Eric L., Austin, Matthew S., "Mobile-Bearing Total Knee Arthroplasty",

vol. 25, No. 6, 2010, pp. 998-1003, "Journal of Arthroplasty", Philadelphia, Pennsylvania.

Fregly, Benjamin, J., Bei, Yanhong, Sylvester, Mark E., "Experimental Evaluation of an Elastic Foundation 3 Model to Predict Contact Pressures in Knee Replacements", vol. 36, No. 11, Nov. 2003, pp. 1659-1668, "Journal of Biomechanics", Gainesville, Florida.

Strickland, M.A., Taylor, M., "In-Silico Wear Prediction for Knee Replacements—Methodology and Corroboration", vol. 42, No. 10, Jul. 2009, "Journal of Biomechanics", Southampton, United Kingdom.

Halloran, Jason P., Easley, Sarah K., Patrella, Anthony J., Rullkoetier, Paul J., "Comparison of Deformable and Elastic Foundation Finite Element Simulations for Predicting Knee Replacement Mechanics", vol. 127, No. 5, Oct. 2005, pp. 813-818, "Journal of Biomechanical Engineering", Denver, Colorado.

Guerinot, Alexandre, E., Magleby, Spencer, P. Howell, Larry L., "Preliminary Design Concepts for Compliant Mechanism Prosthetic Knee Joints", vol. 2B, pp. 1103-1111, 2004, "Proceedings of the ASME Design Engineering Technical Conference", Provo, Utah.

Walker, Peter, S., Sathasivam, Shivani, "The Design of Guide Surfaces for Fixed-Bearing and Mobile-Bearing Knee Replacements", vol. 32, No. 1, pp. 27-34, Jan. 1999, "Journal of Biomechanics", Middlesex, United Kingdom.

Wenzel, SA and Shepherd, D.ET, "Contact Stresses in lumbar Total Disc Arthroplasty", vol. 17, No. 3, 2007, pp. 169-173, "Bio-medical Materials and Engineering", Edgbaston, UK.

Clewiow, J.P., Pyllos, T. and Shepherd, D.ET, "Soft layer Bearing Joins for Spine Arthroplasty", vol. 29, No. 10, Dec. 2008, pp. 1981-1985, "Materials and Design", Edgbaston, UK.

Parea, Philippe E., Chana, Frank W., Bhattacharyya, Sanghita and Goei, Vijay K., "Surface Slide Track Mapping of Implants for Total Disc Arthroplasty", vol. 42, No. 2, Jan. 19, 2009, pp. 131-139, "Journal of Biomechanics", [online] [retrieved Feb. 19, 2010].

Dooris, Andrew P., Goei, Vijay K., Todd, Dwight T., Grosland, Nicole M., Wilder, David G., "Load Sharing in a Lumbar Motion Segment Implanted with an Artificial Disc Under Combined Sagittal Plane Loading", BED-vol. 42, 1999, pp. 277-278, American Society of Mechanical Engineers, Iowa City, Iowa.

Walter, A., Plitz, W., "Wear Characteristics of Ceramic-to-Ceramic Hip Joint Endoprostheses", Transactions of the Annual Meeting of the Society for Biomaterials in Conjunction with the Internat., vol. 8, p. 178, Apr. 1985, Conference: Transactions of the Eleventh Annual Meeting of the Society for Biomaterials, in Conjunction with the Seventeenth International Biomaterials Symposium, Published by Society for Biomaterials, San Antonio, Texas.

Hutter, K.J., Bruckmann, H., Redig, H., Weber, U., "Development and Clinical Testing of Carbon 1 Implants for Orthopedic Surgery", Schunk and Ebe G.m.b.H., Giessen (Germany, F.R.), Bundesministerium fuer Forschung und Technologie, Bonn-Bad Godesberg (Germany, F. R.), p. 112, Jan. 1981.

St. John, K.R., Zardiackas, L.D., Poggie, RA, "Wear Evaluation of Cobalt-Chromium Alloy for Use in a Metal-on-Metal Hip Prosthesis", vol. 68, pp. 1-14, Jan. 15, 2004, "Journal of Biomedical Materials Research, Part B, Applied Biomaterials", Wiley Periodicals, United States.

Scholes, S.C., Burgess, I.C., Marsden, H.R., Unsworth, A., Jones, E., Smith, N., "Compliant Layer Acetabular Cups: Friction Testing of a Range of Materials and Designs for a New Generation of Prosthesis that Mimics the Natural Joint", vol. 220, pp. 583-596, Jul. 2006, "Proceedings of the Institution of Mechanical Engineers, Part H", Journal of Engineering in Medicine, United Kingdom.

Gao, L., Wang, F., Yang, R., Jin, Z., "Effect of 3D Physiological Loading and Motion on Elastohydrodynamic Lubrication of Metal-on-Metal Total Hip Replacements", vol. 31, pp. 720-729, 2009, "Medical Engineering and Physics".

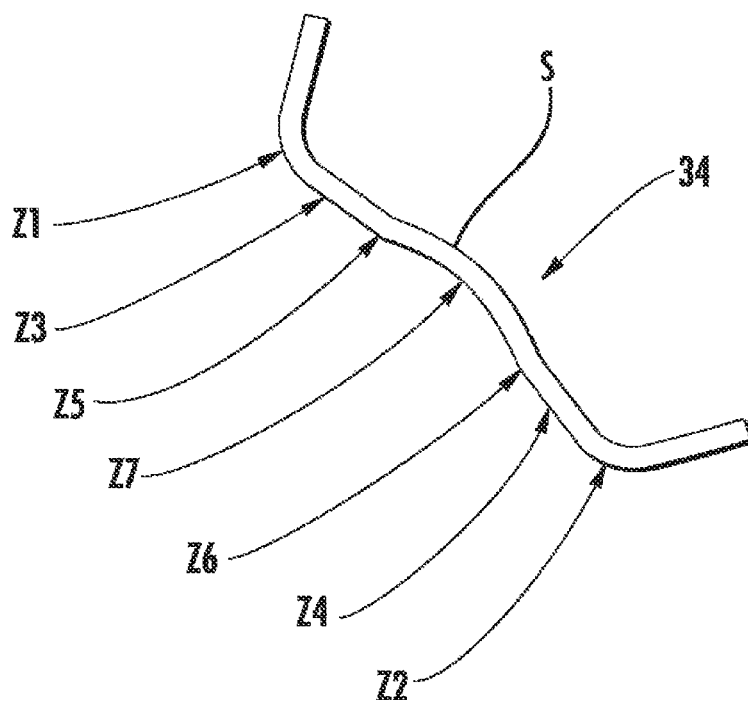


FIG. 1

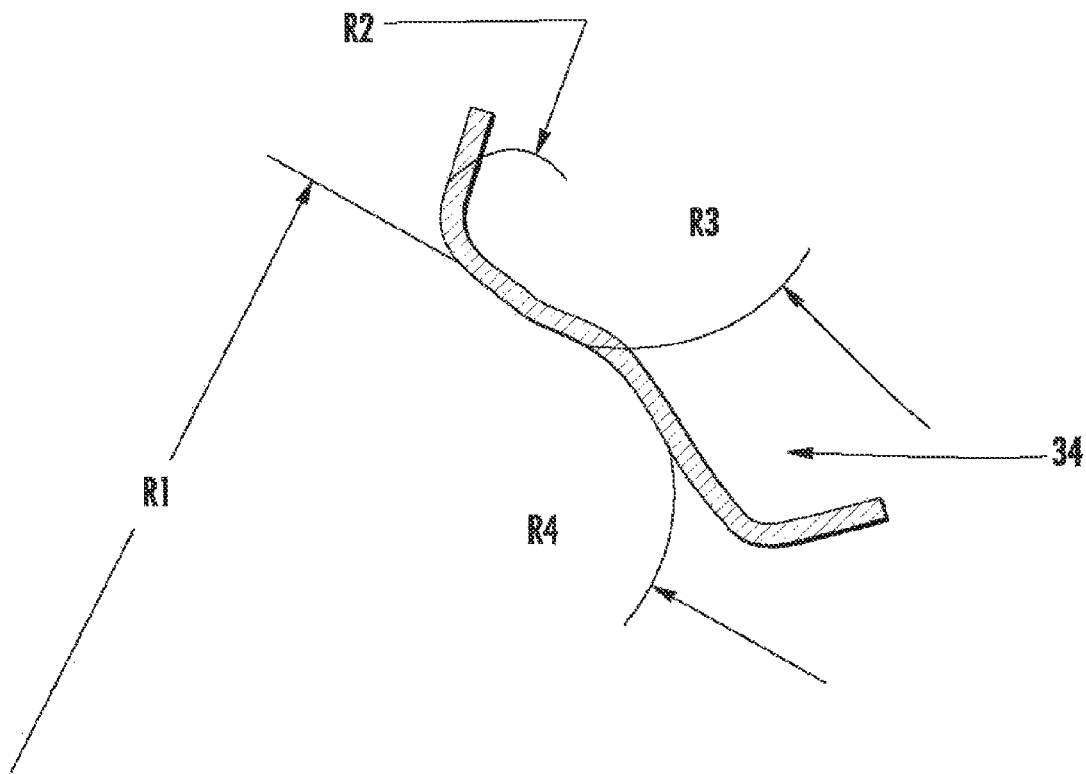


FIG. 2

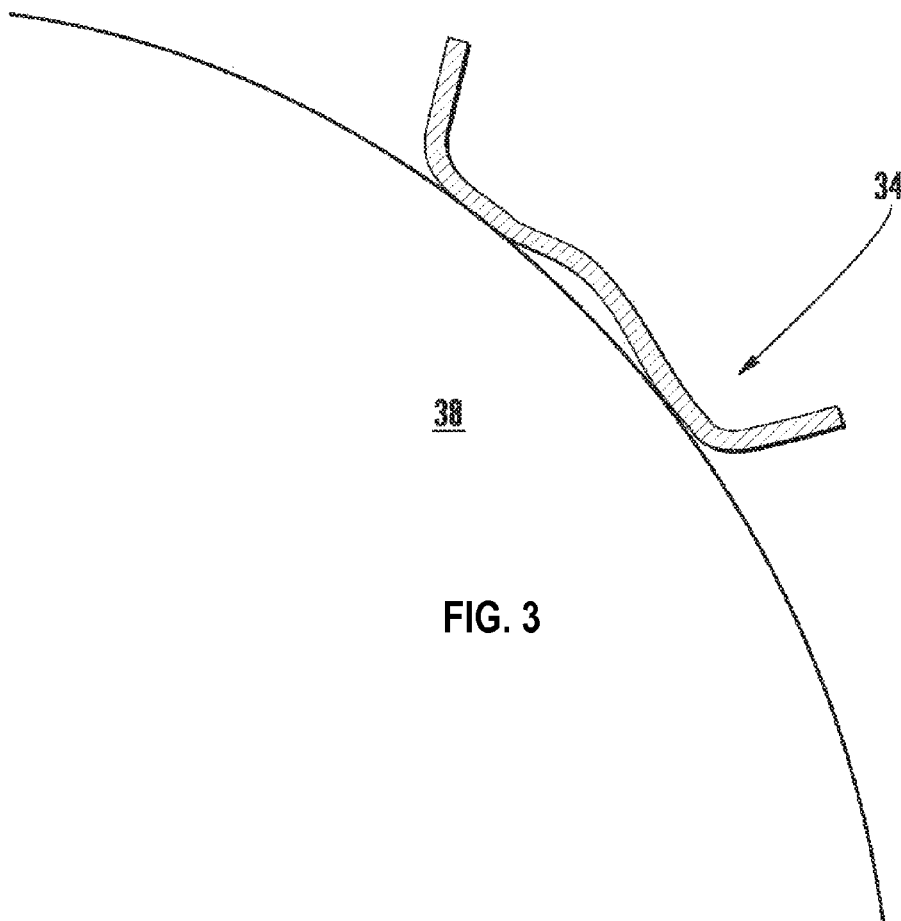


FIG. 3



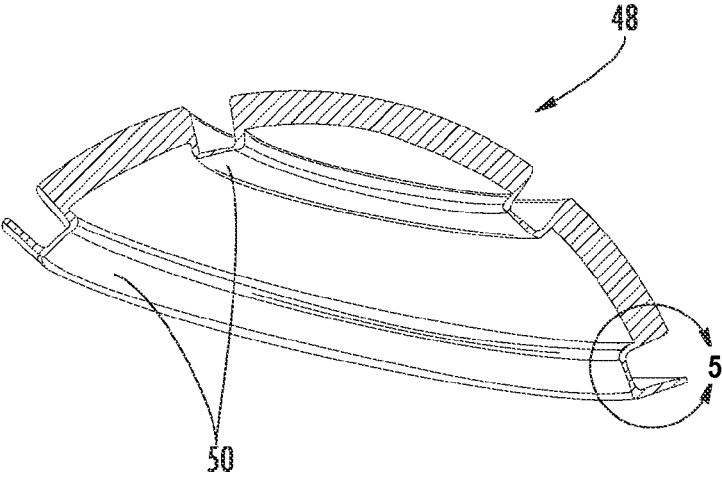


FIG. 4

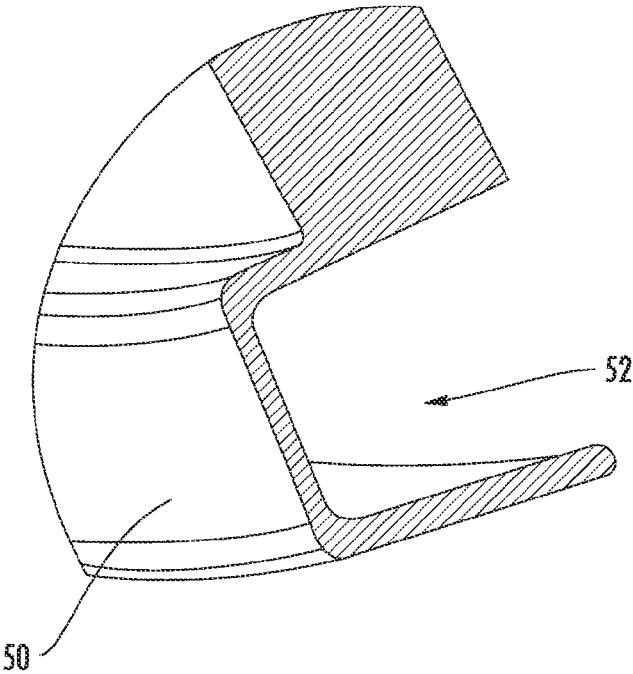


FIG. 5

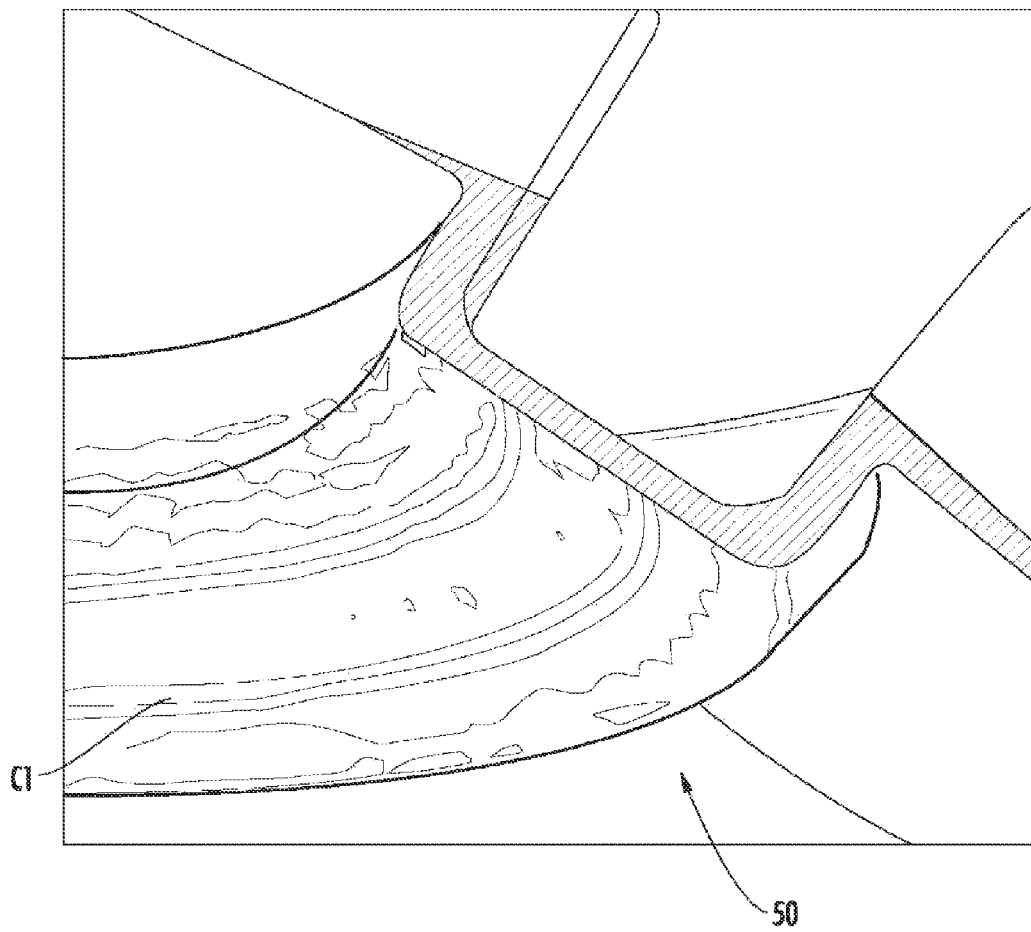


FIG. 6

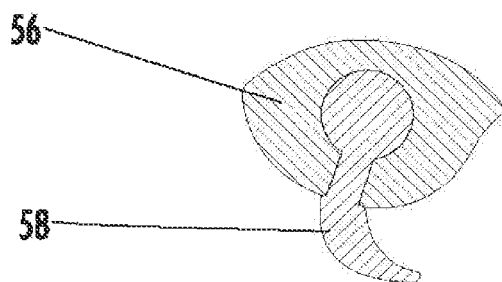


FIG. 8

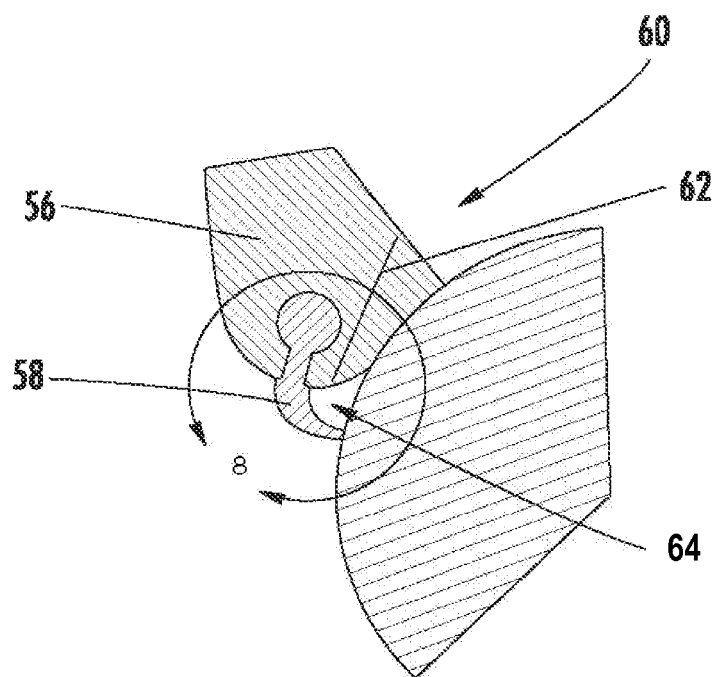
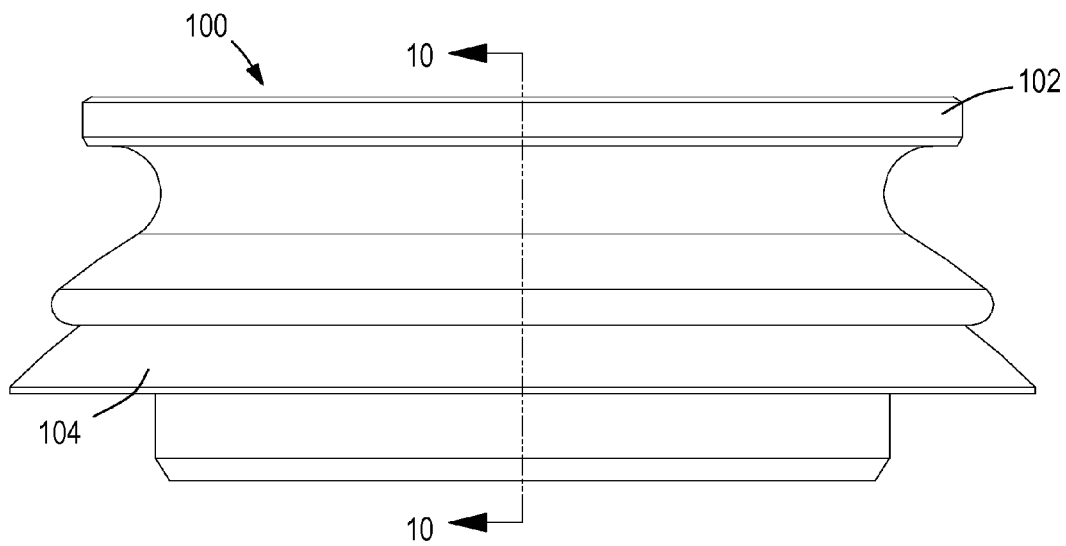


FIG. 7



**FIG. 9**

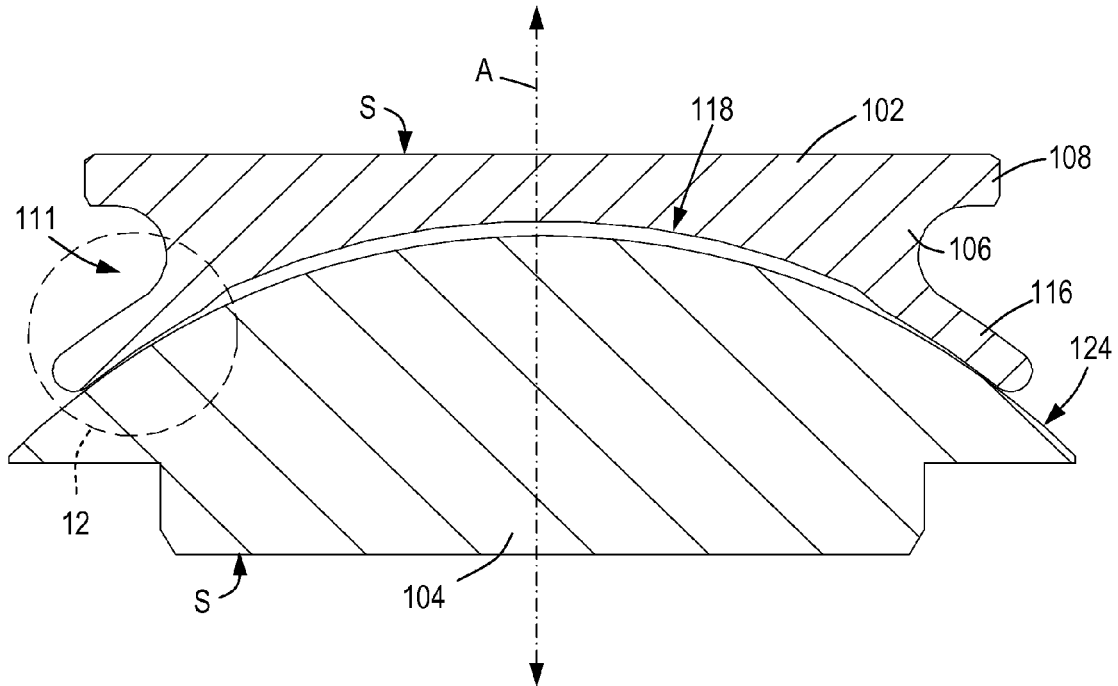


FIG. 10

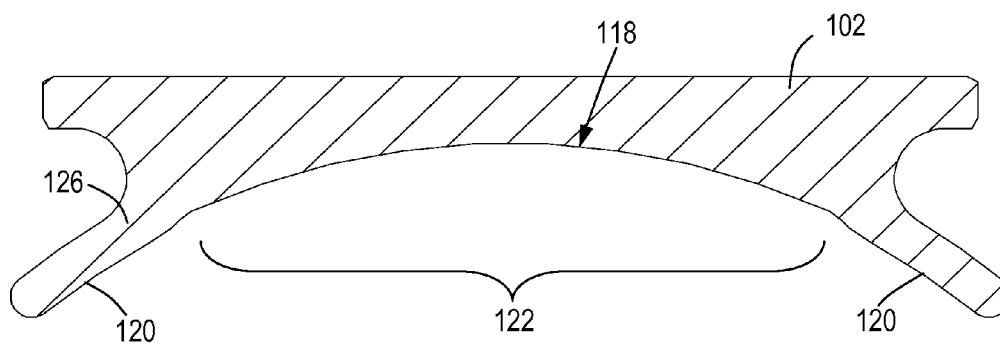


FIG. 11

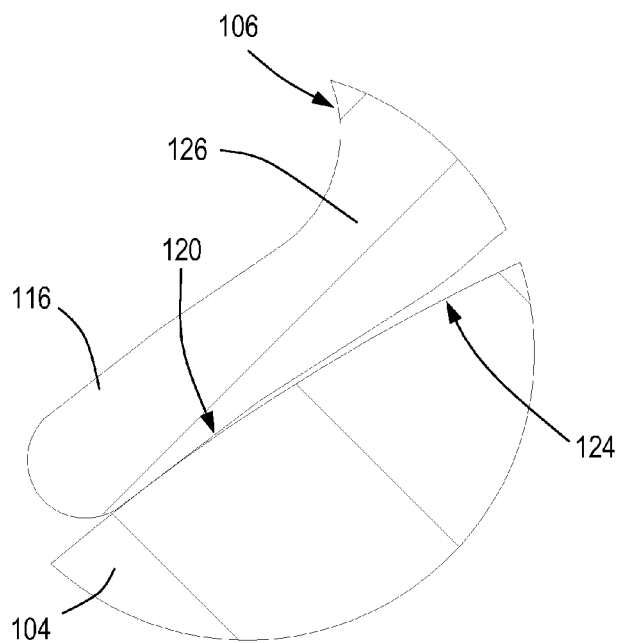


FIG. 12

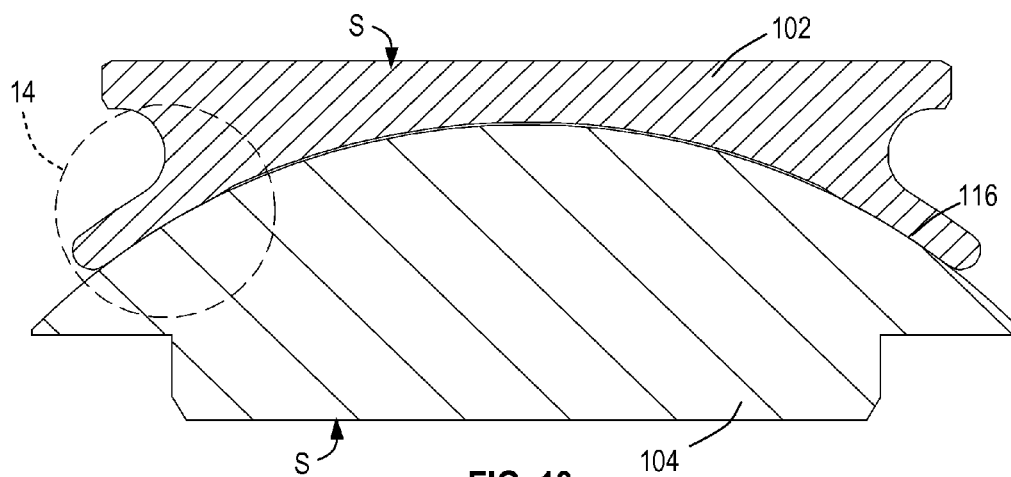


FIG. 13

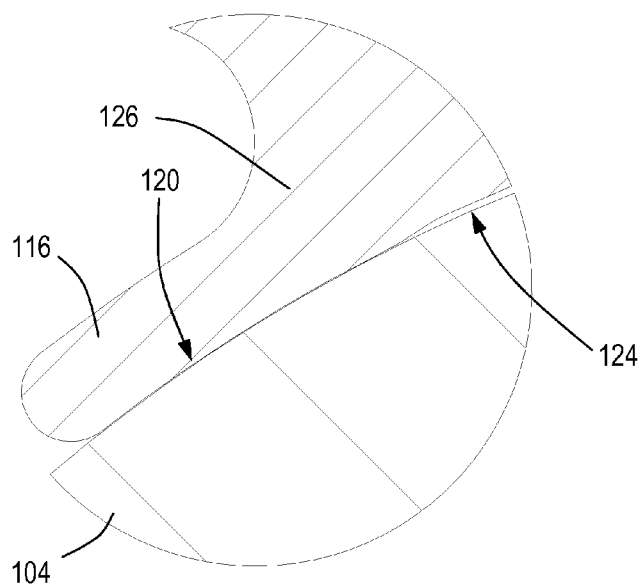


FIG. 14

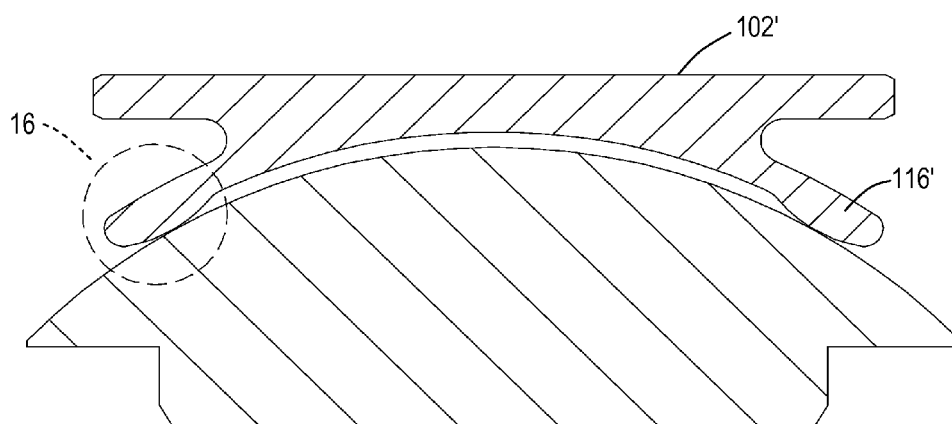


FIG. 15

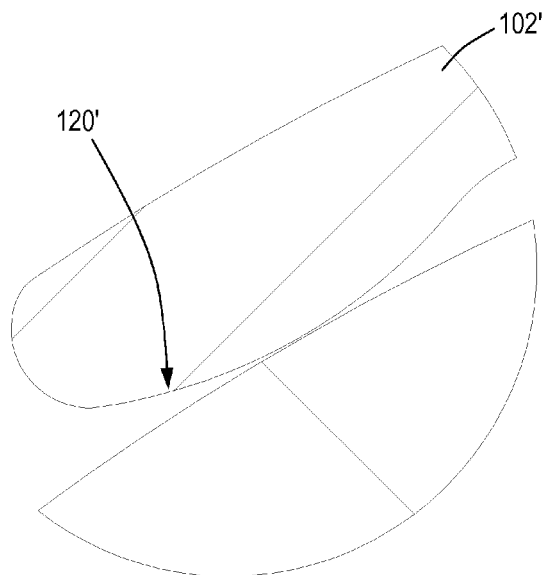


FIG. 16

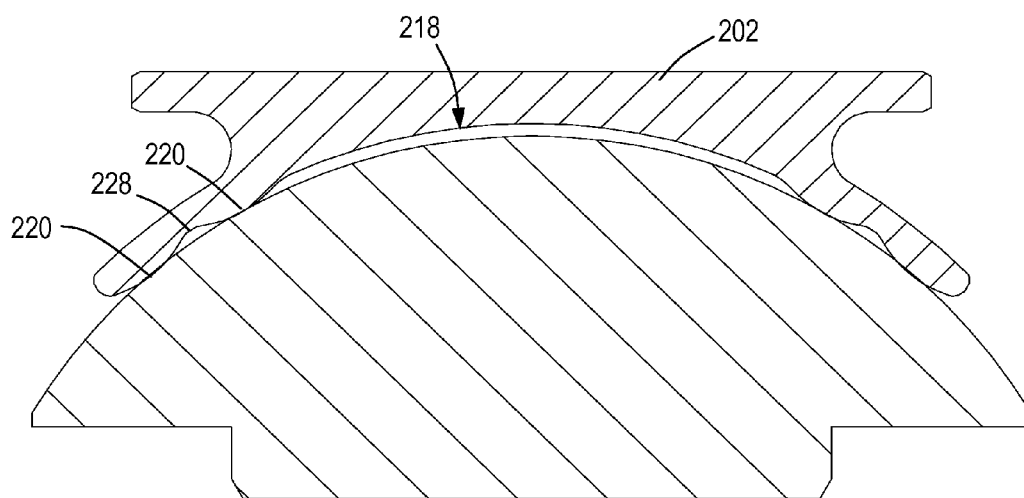


FIG. 17

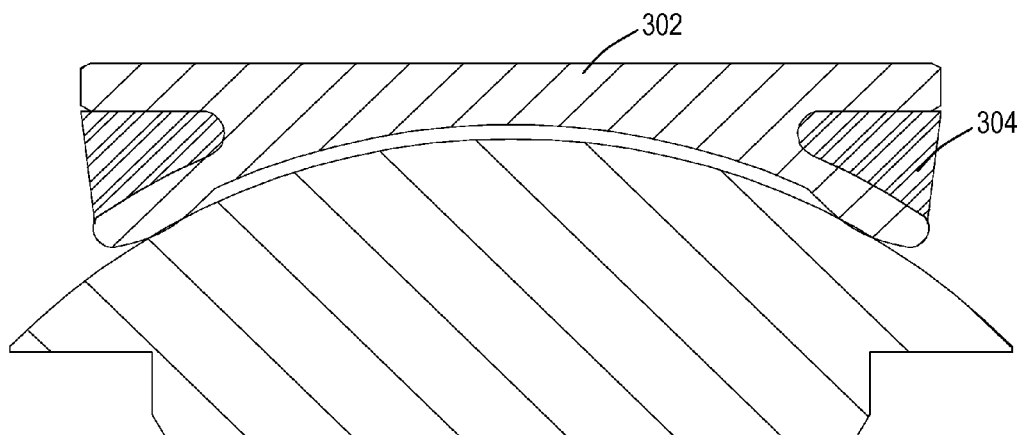


FIG. 18



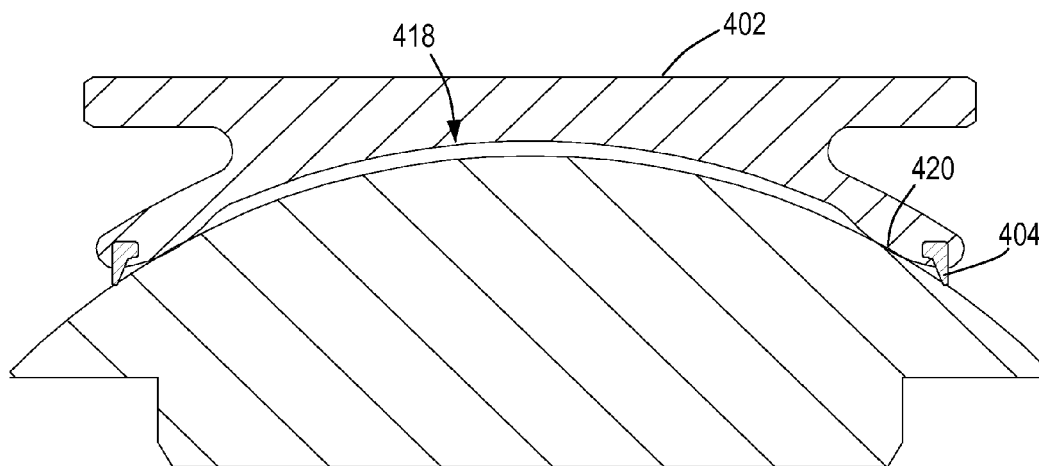


FIG. 19

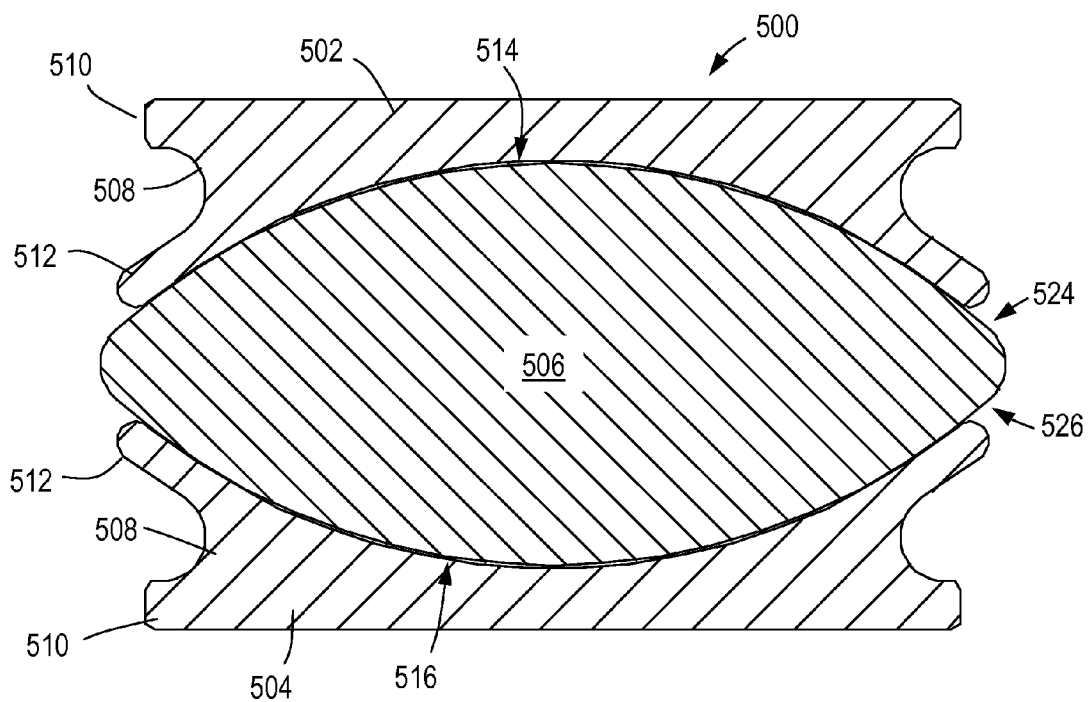
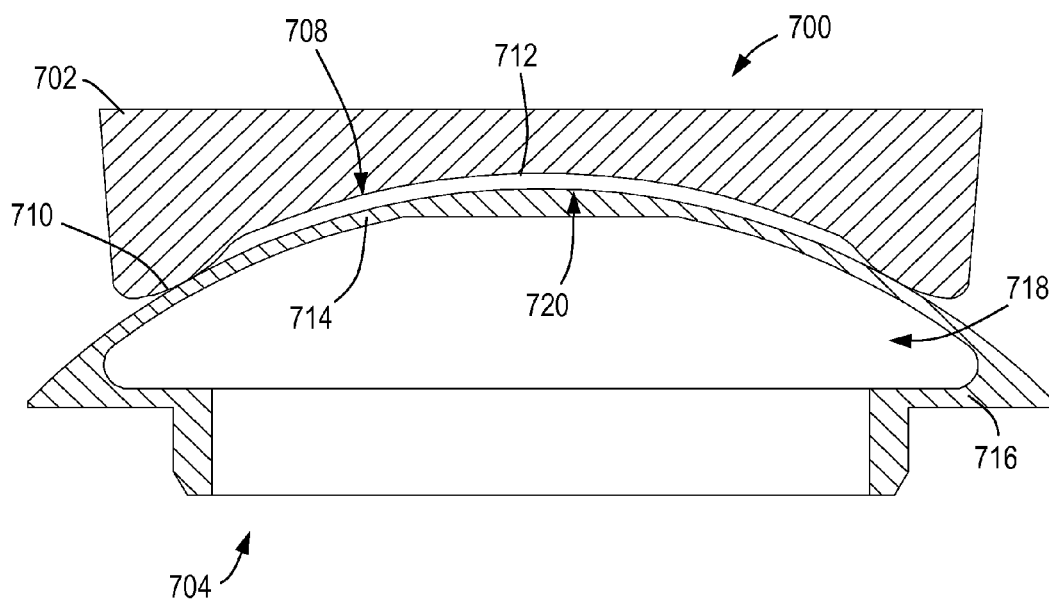
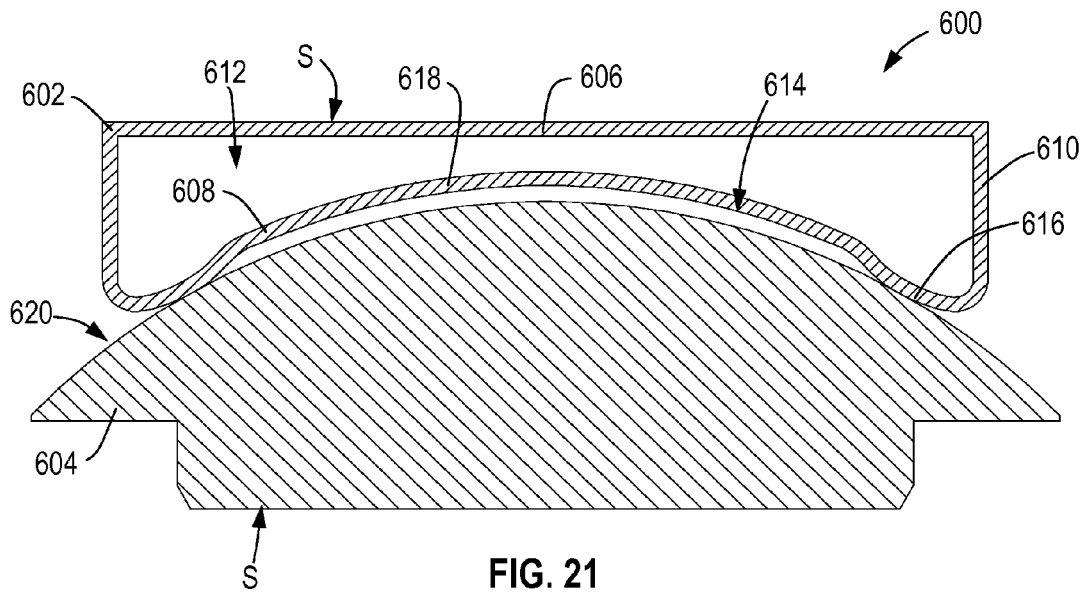


FIG. 20



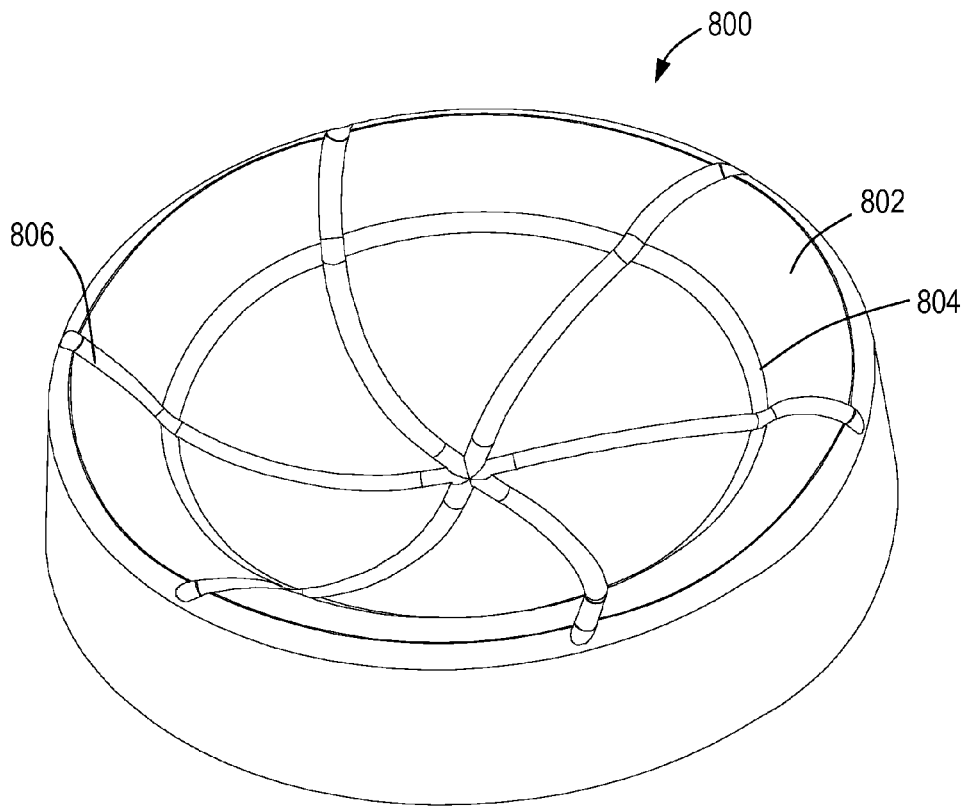


FIG. 23

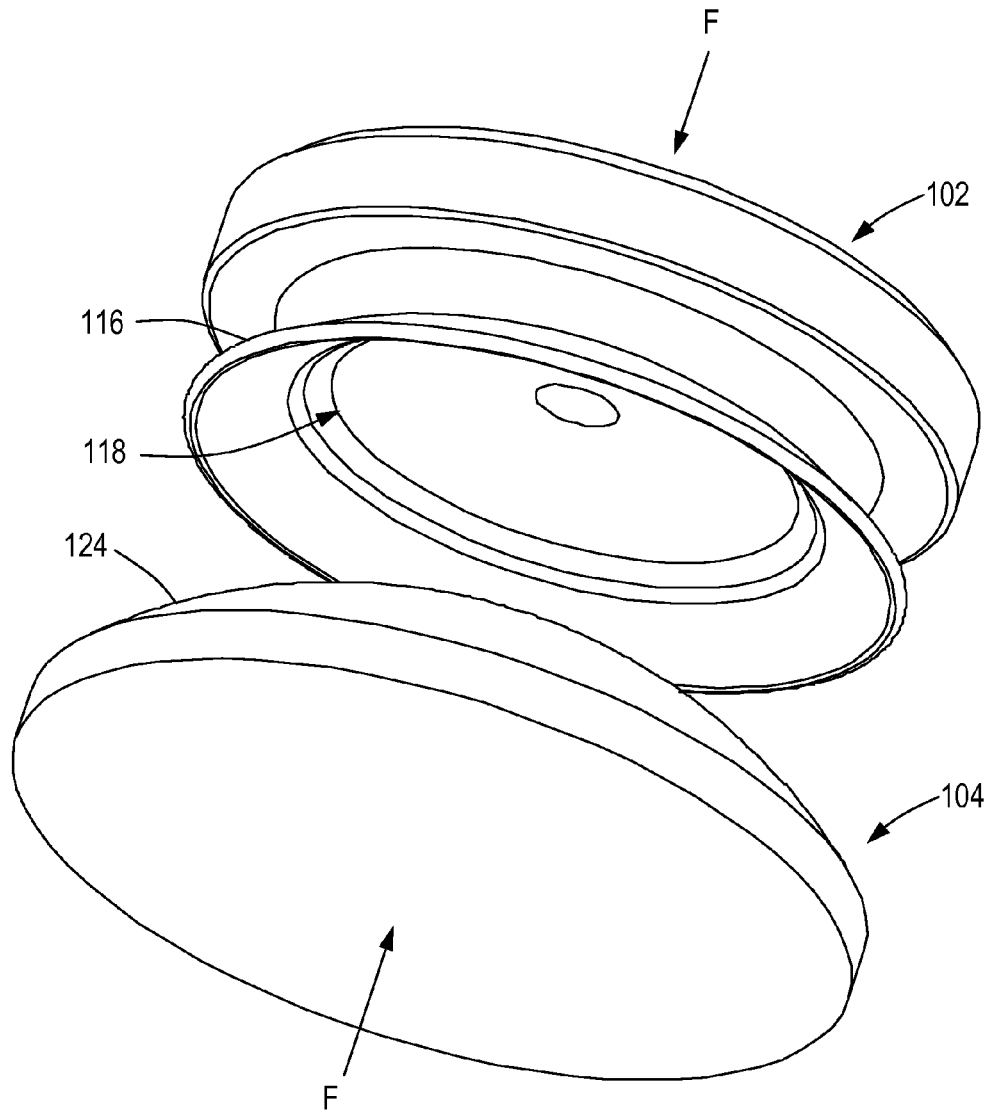


FIG. 24

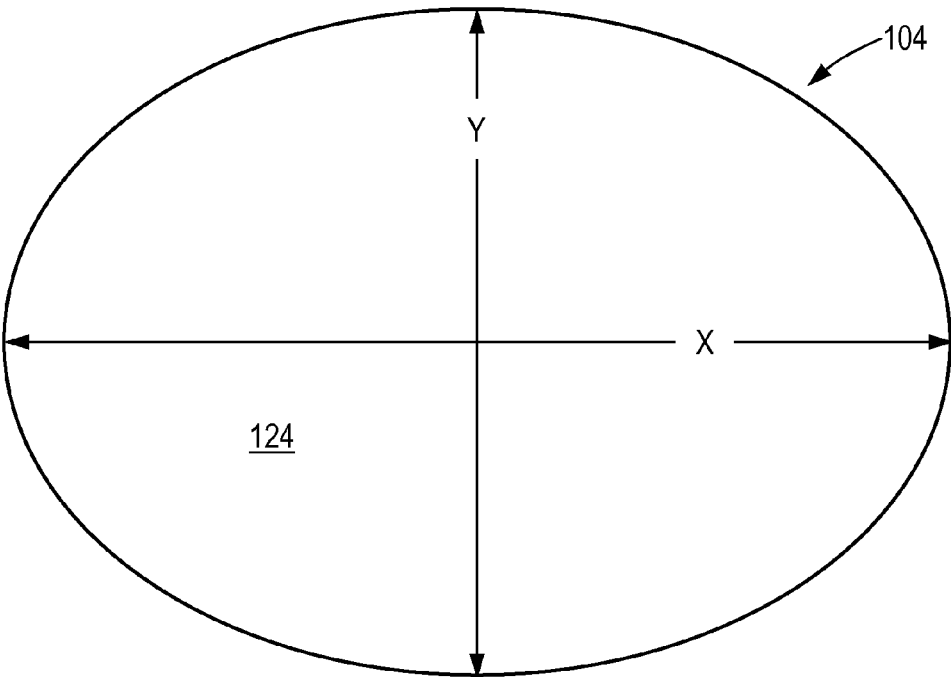


FIG. 25

FIG. 26

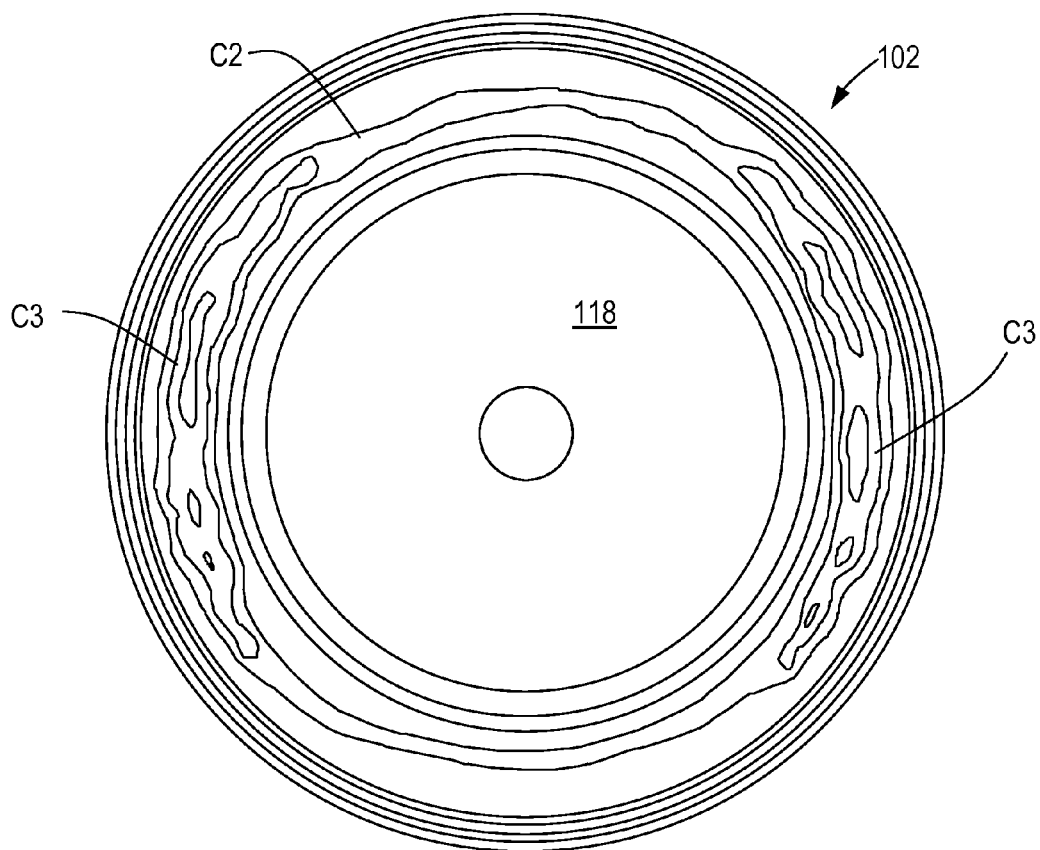
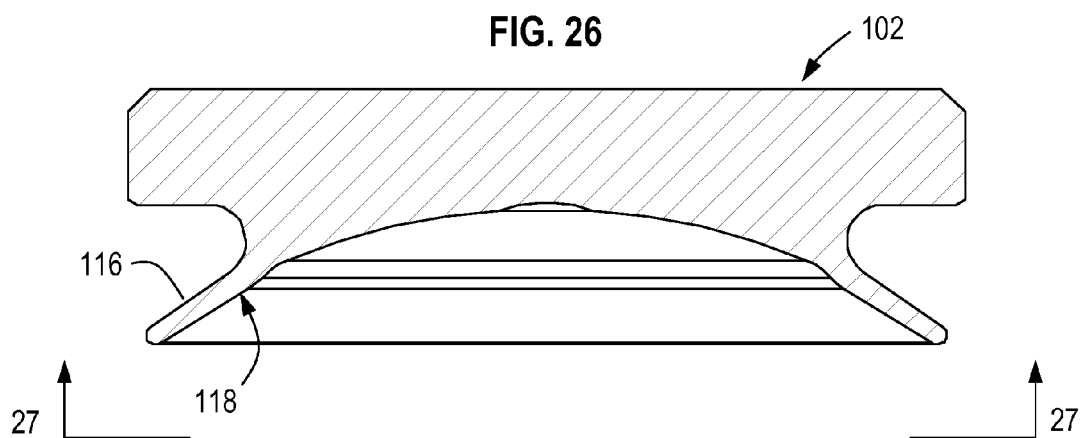


FIG. 27

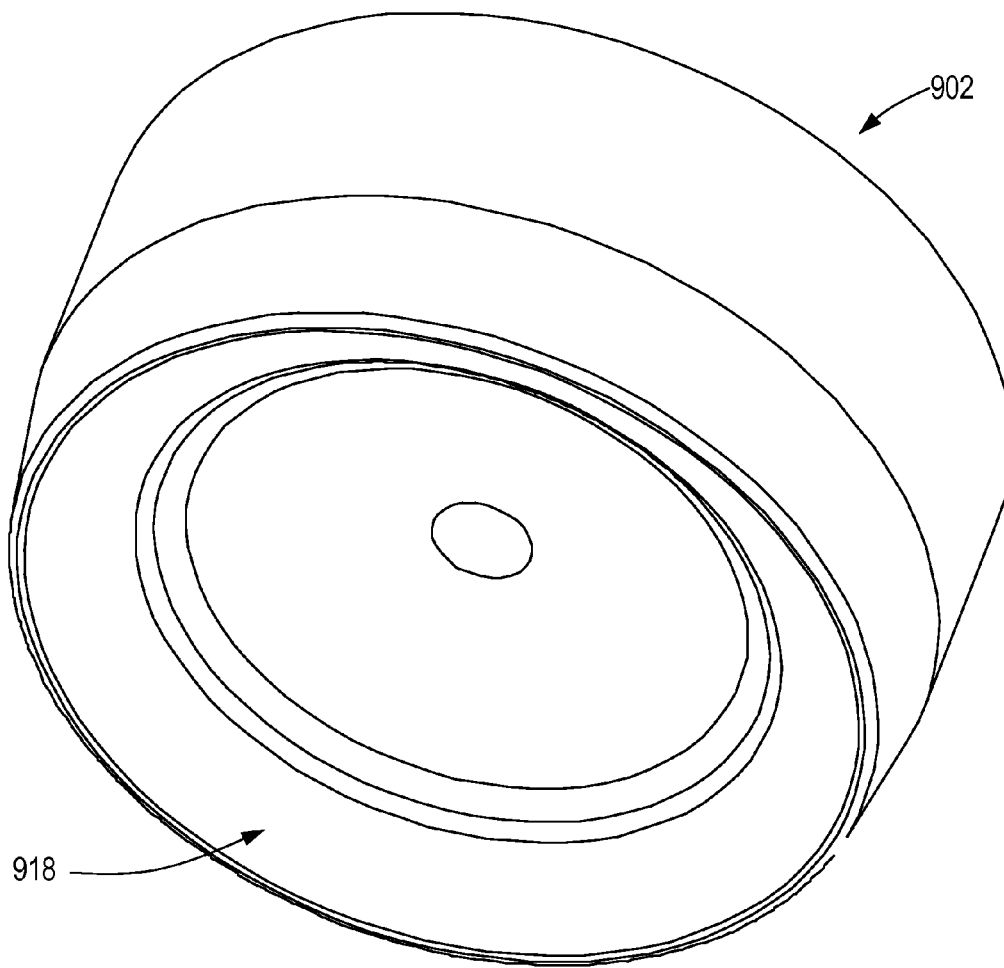
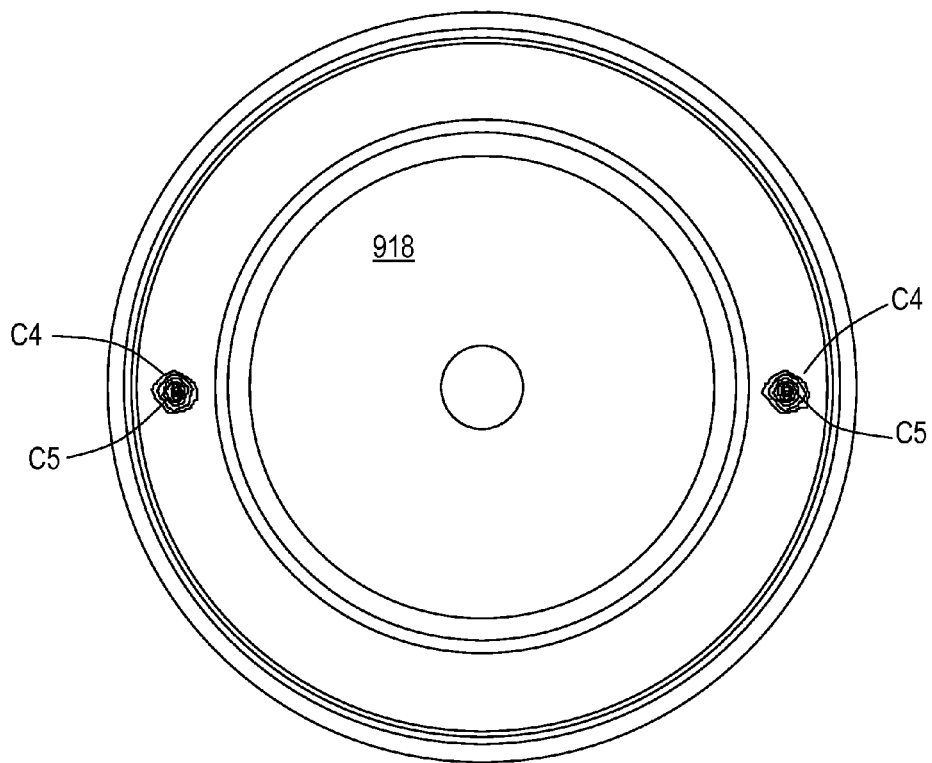
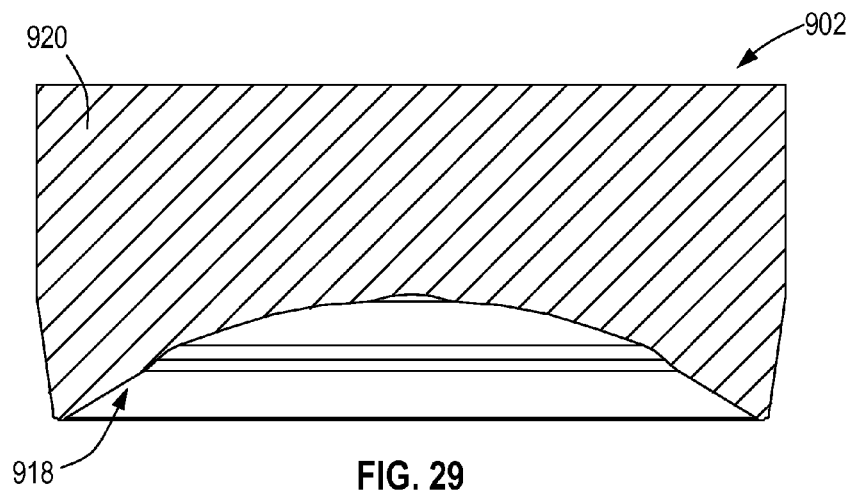


FIG. 28





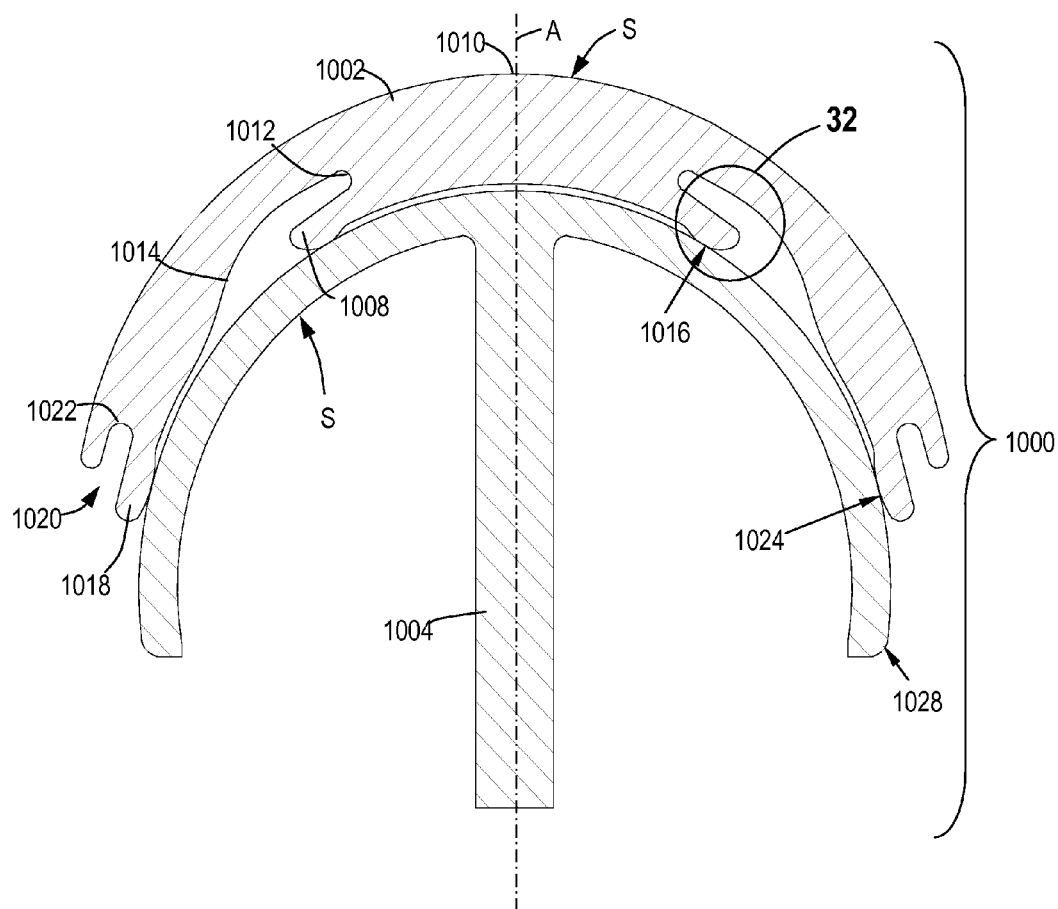


FIG. 31

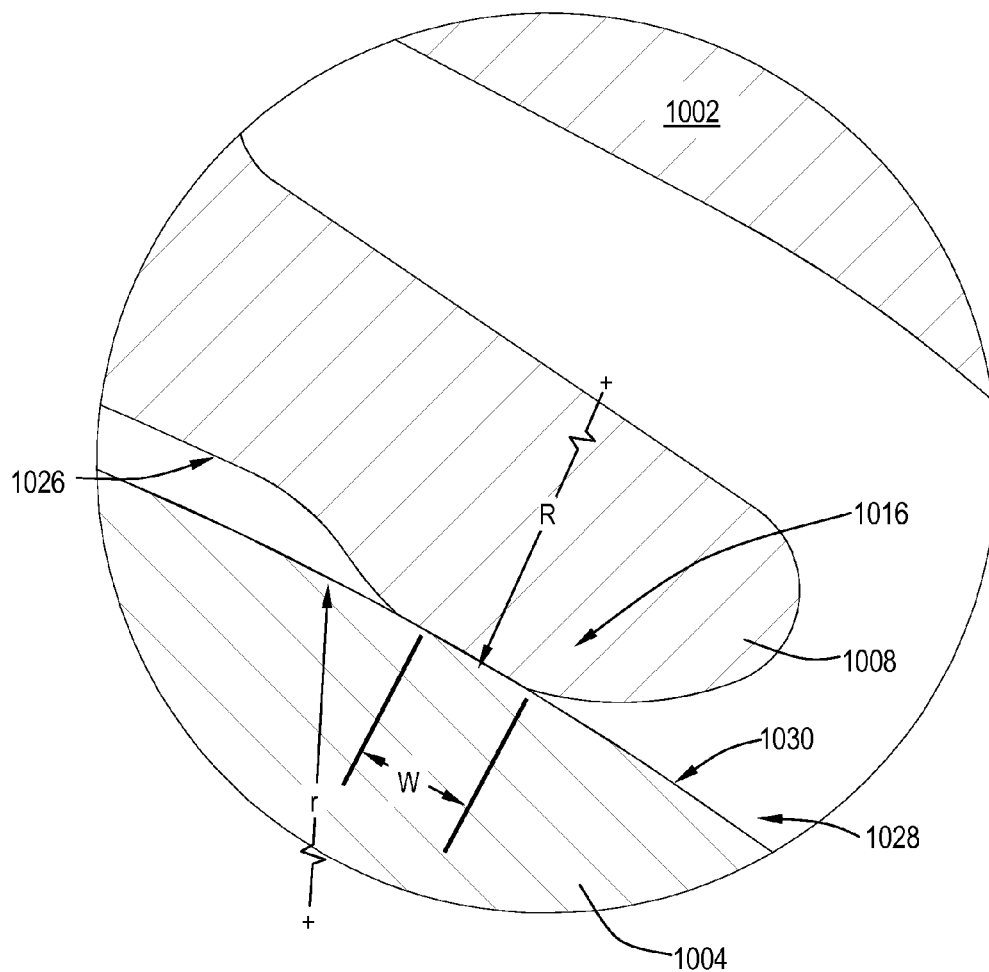


FIG. 32

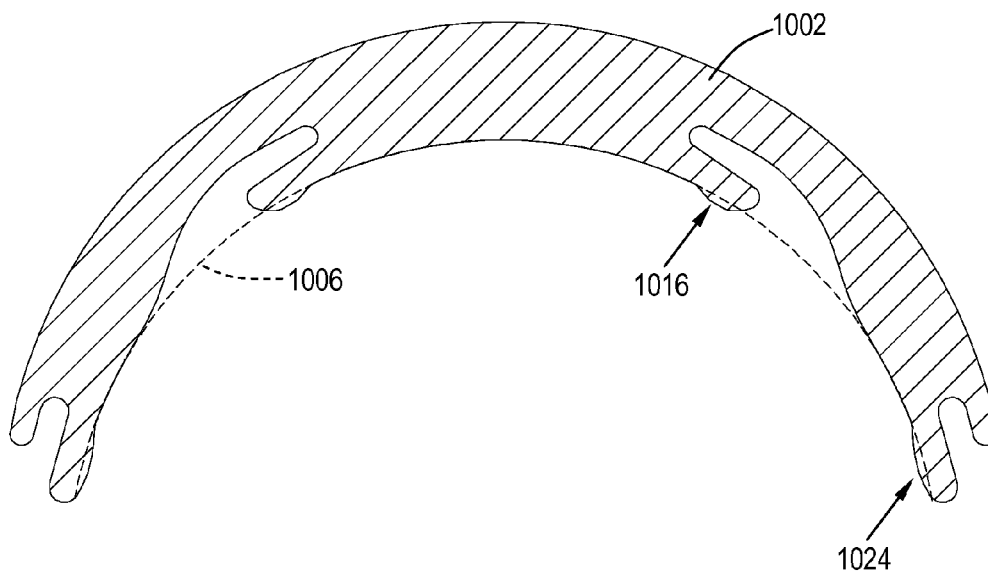
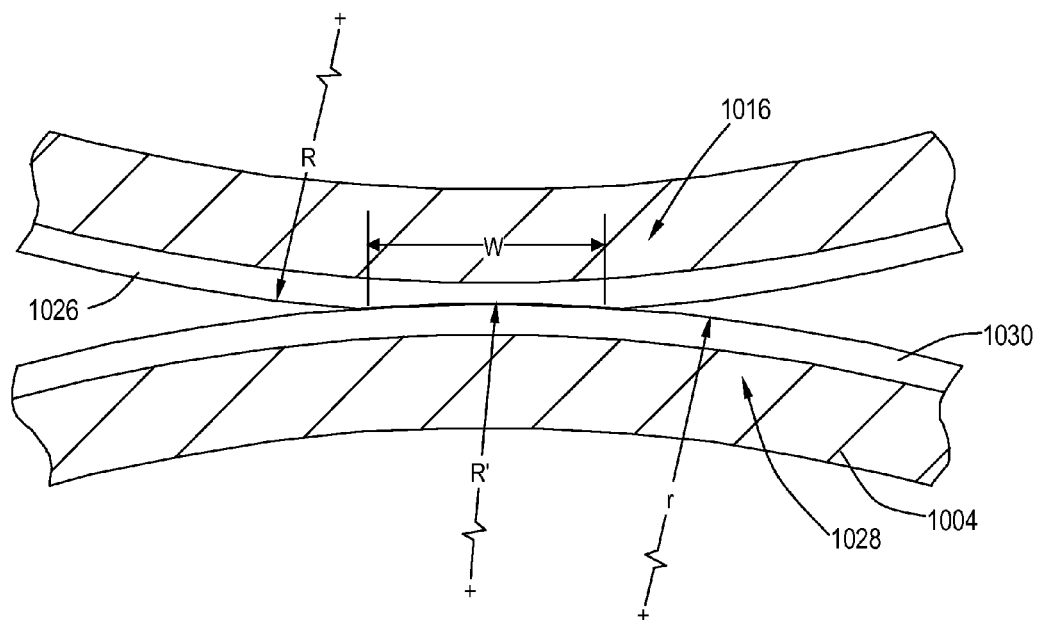
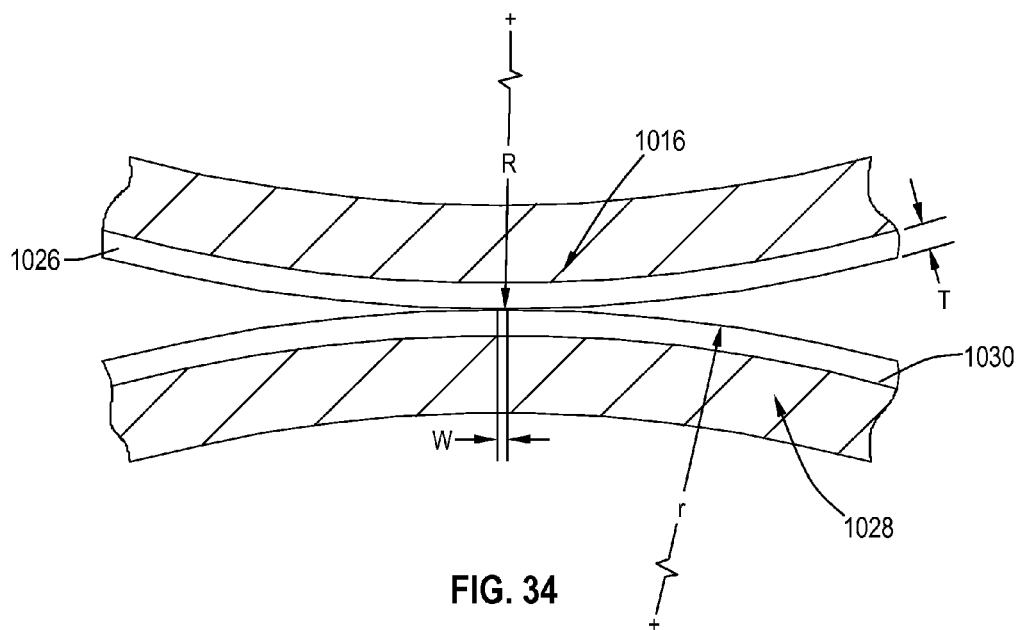


FIG. 33



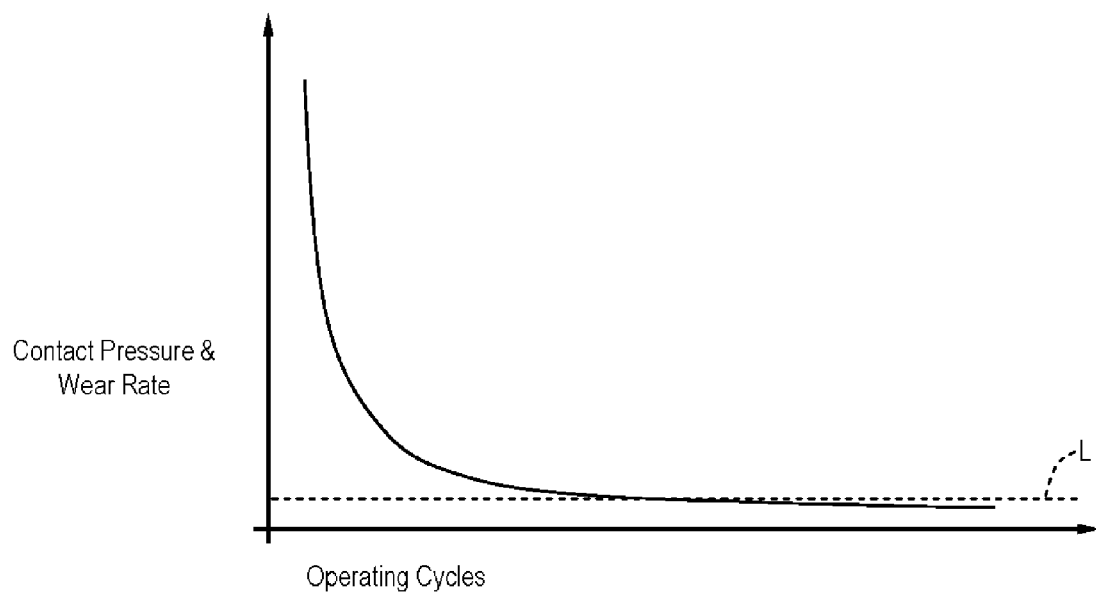


FIG. 36

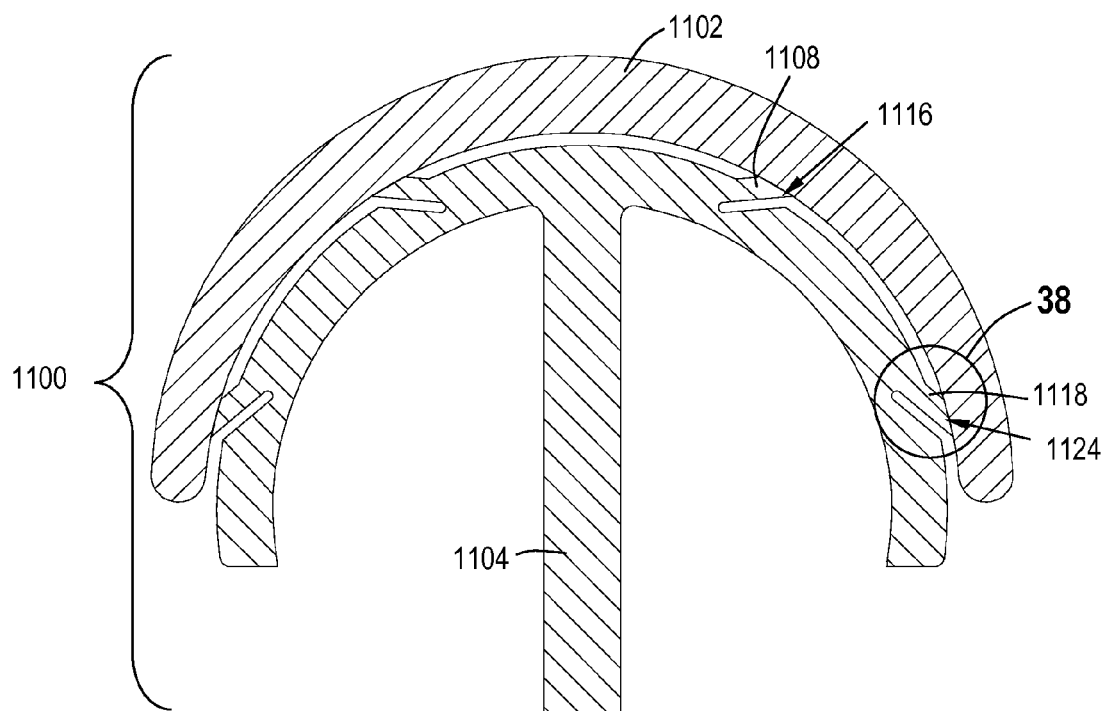


FIG. 37

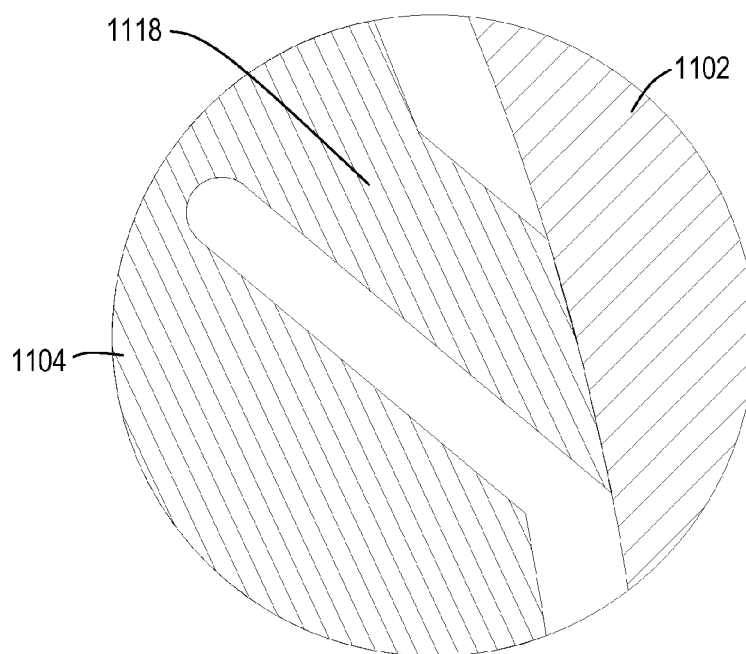


FIG. 38

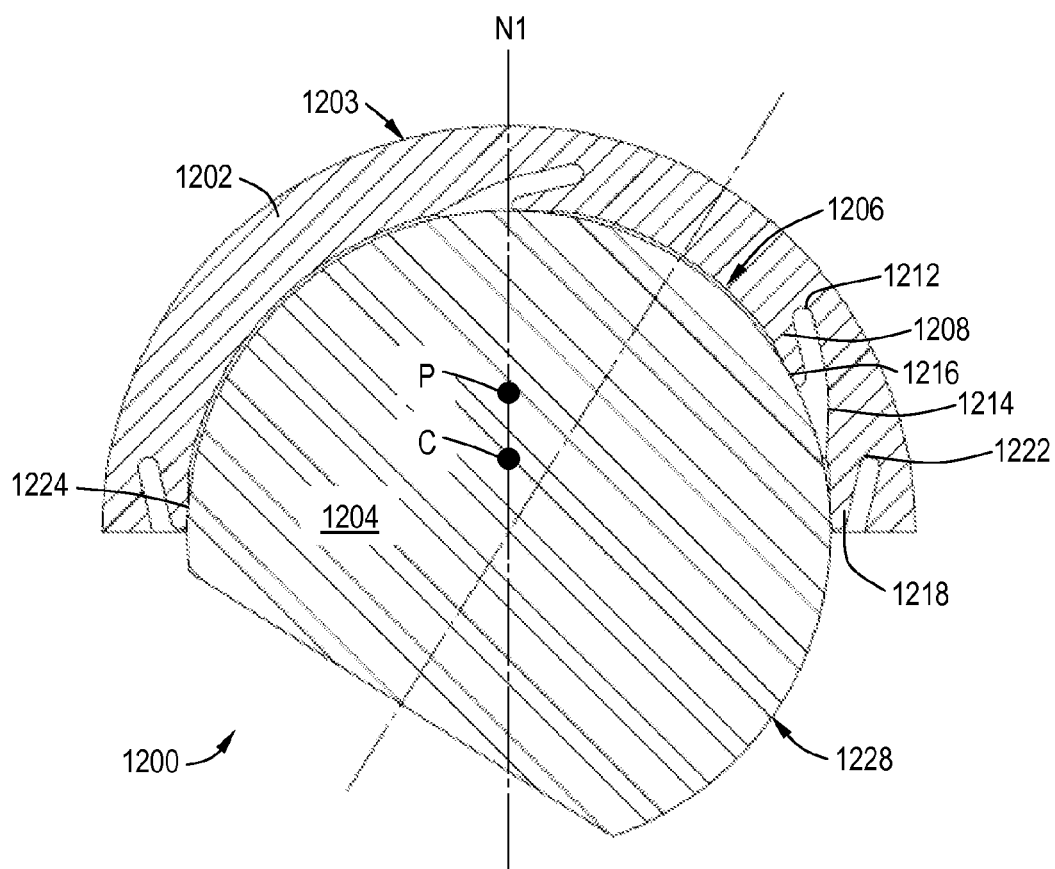


FIG. 39

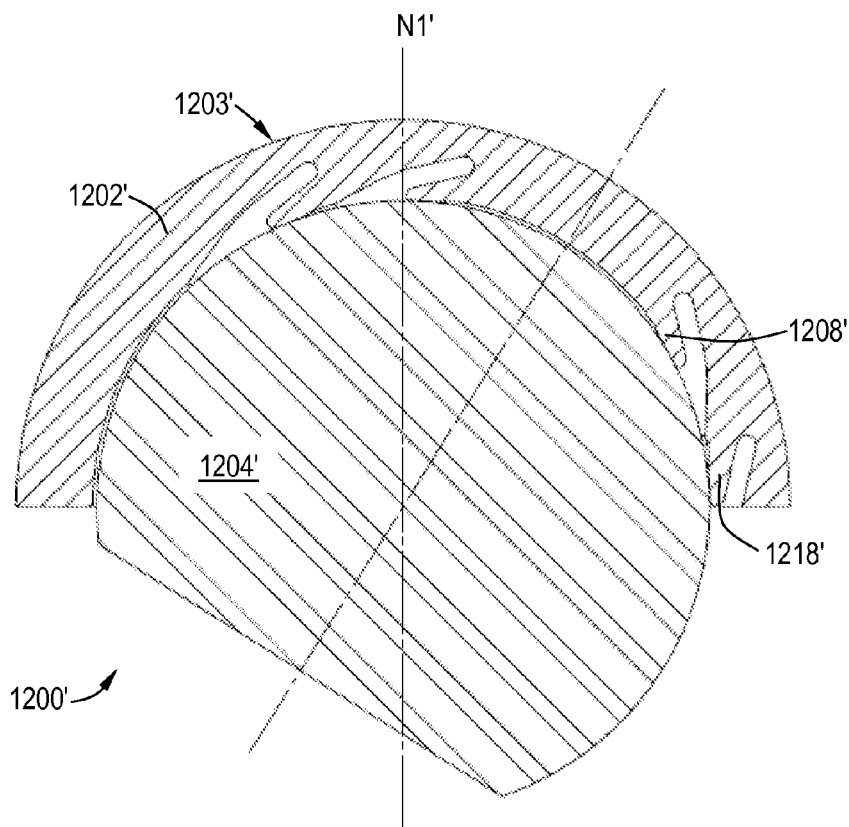


FIG. 40



FIG. 41

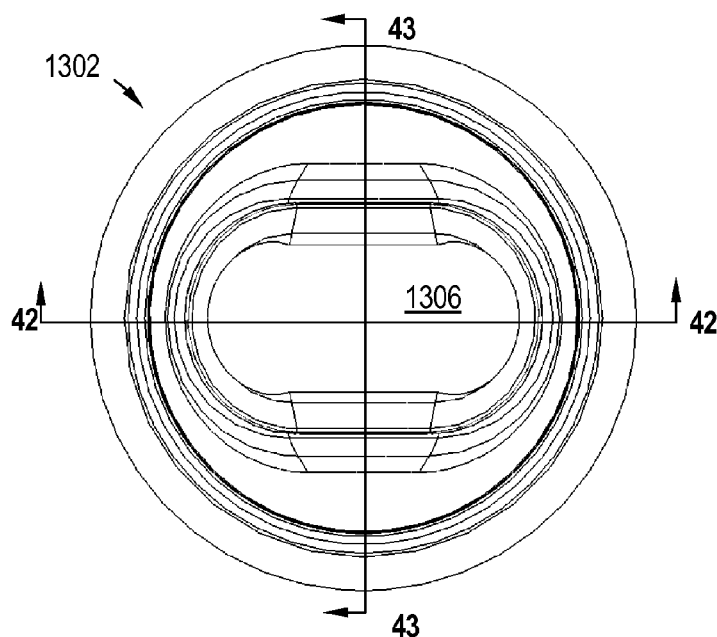


FIG. 42

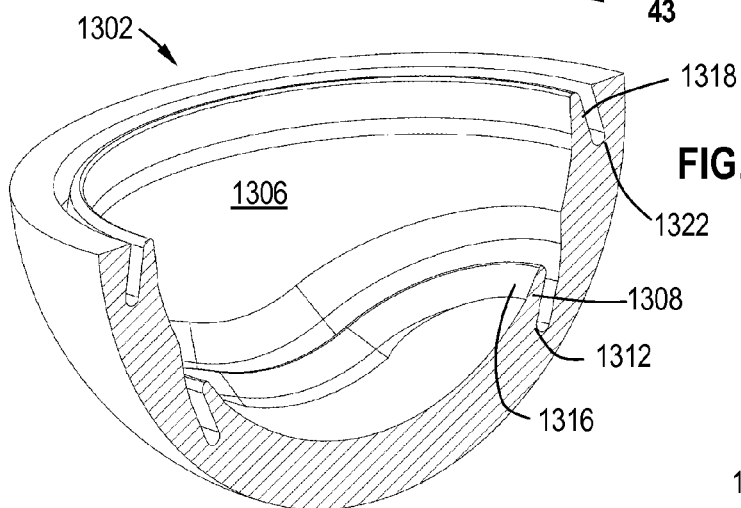
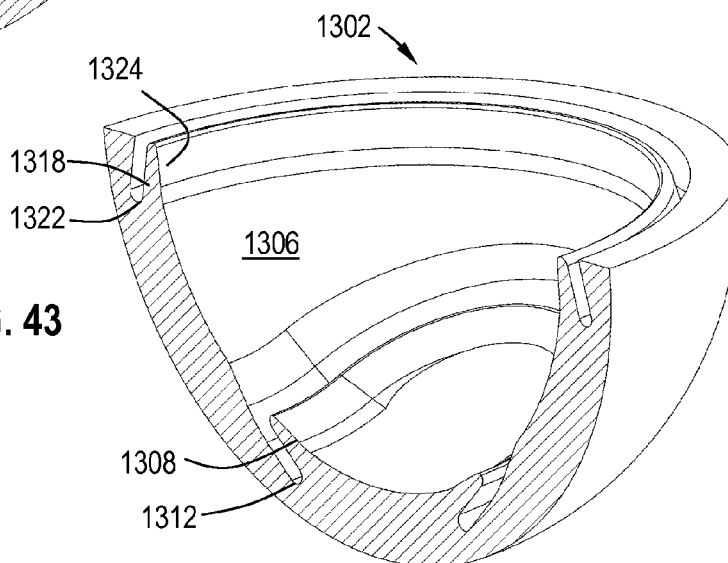


FIG. 43



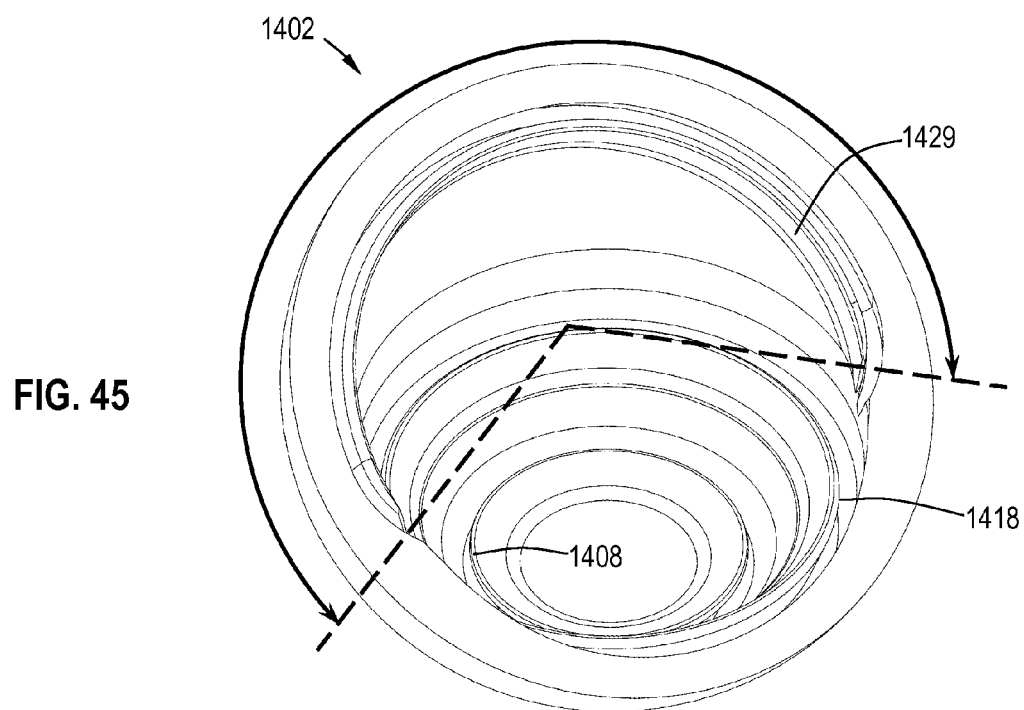
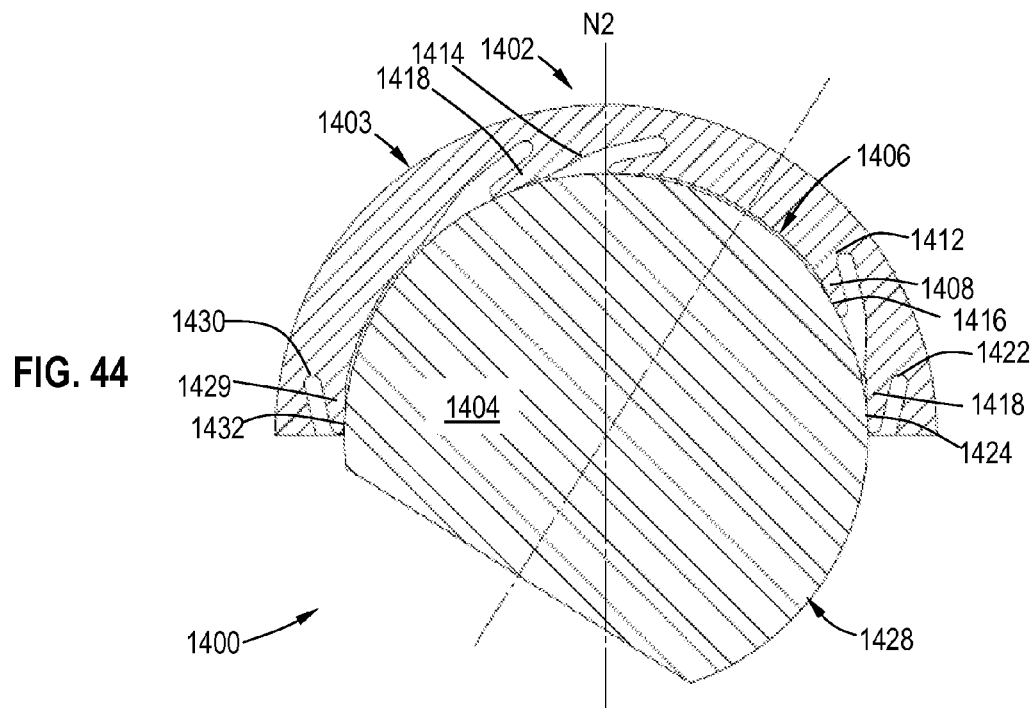


FIG. 46

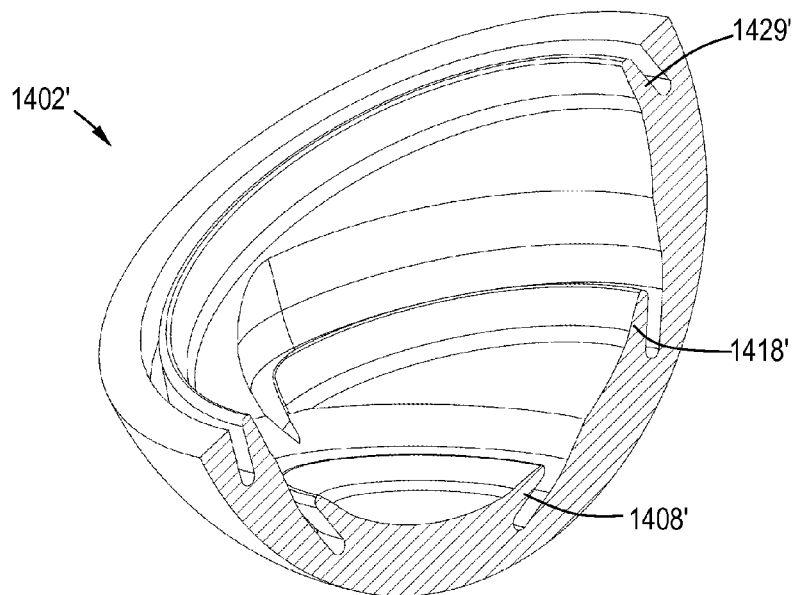
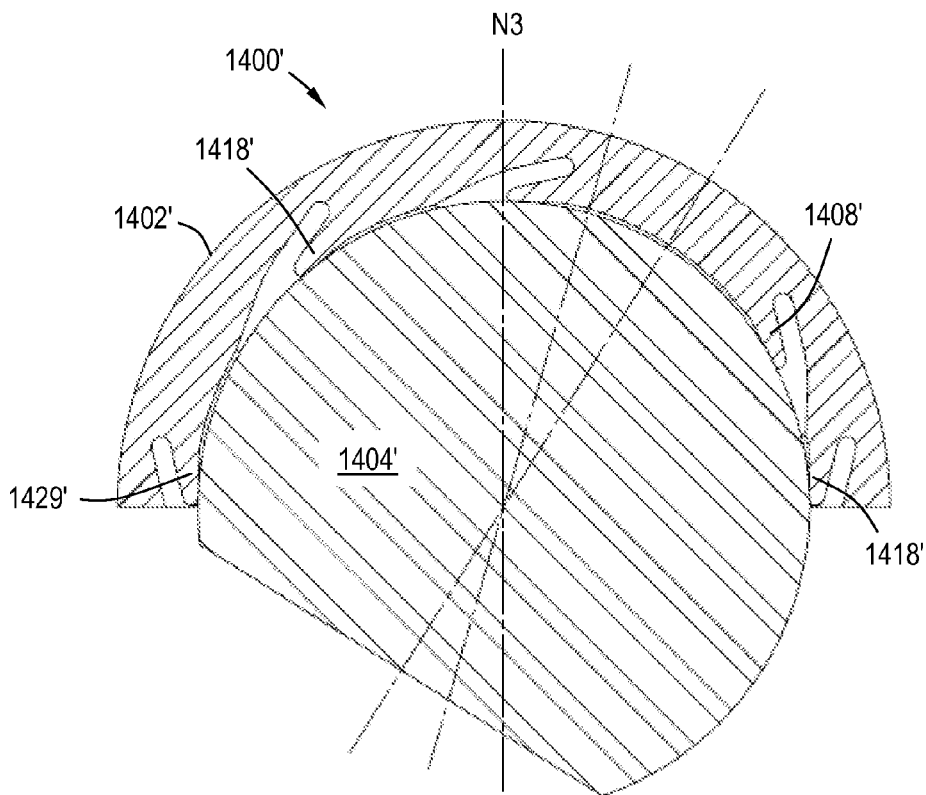


FIG. 47



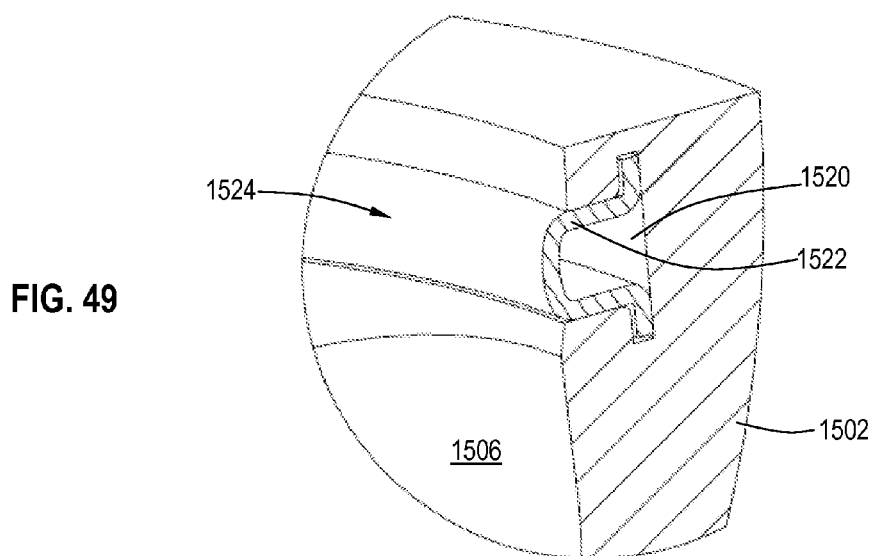
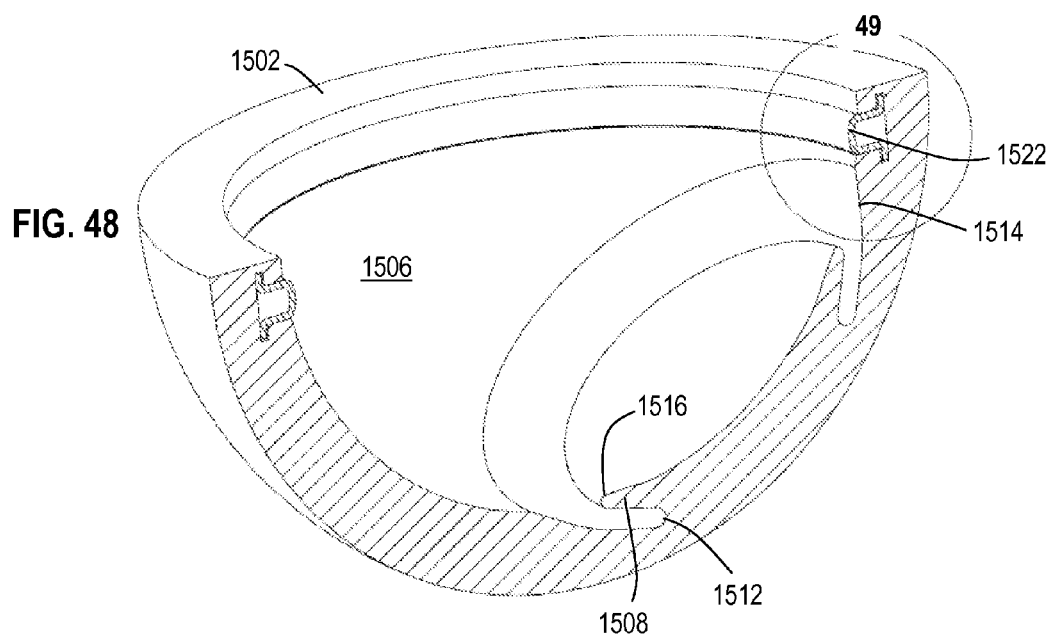


FIG. 50

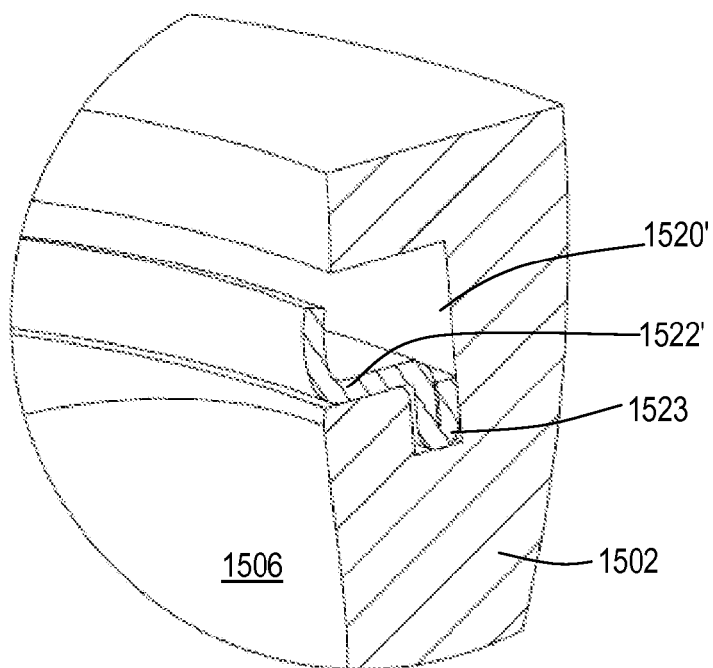
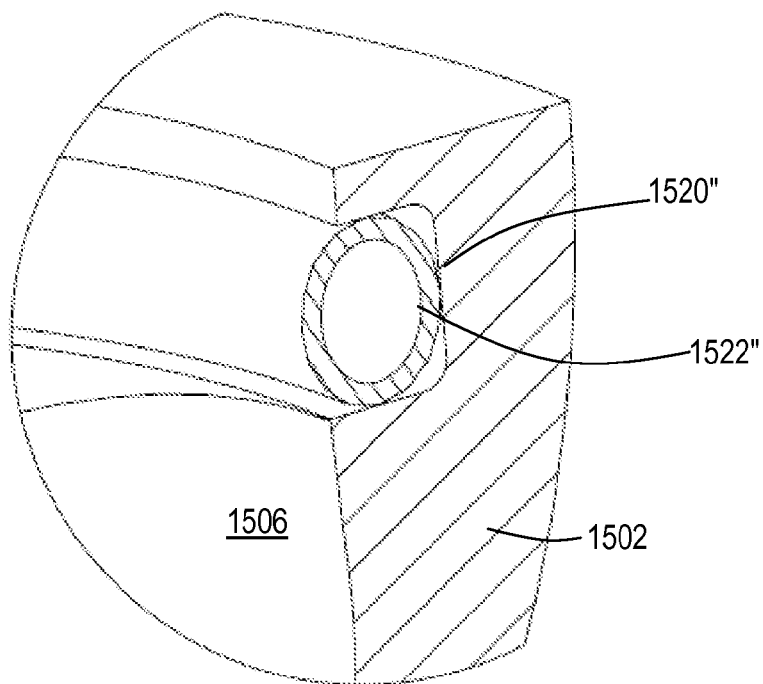


FIG. 51



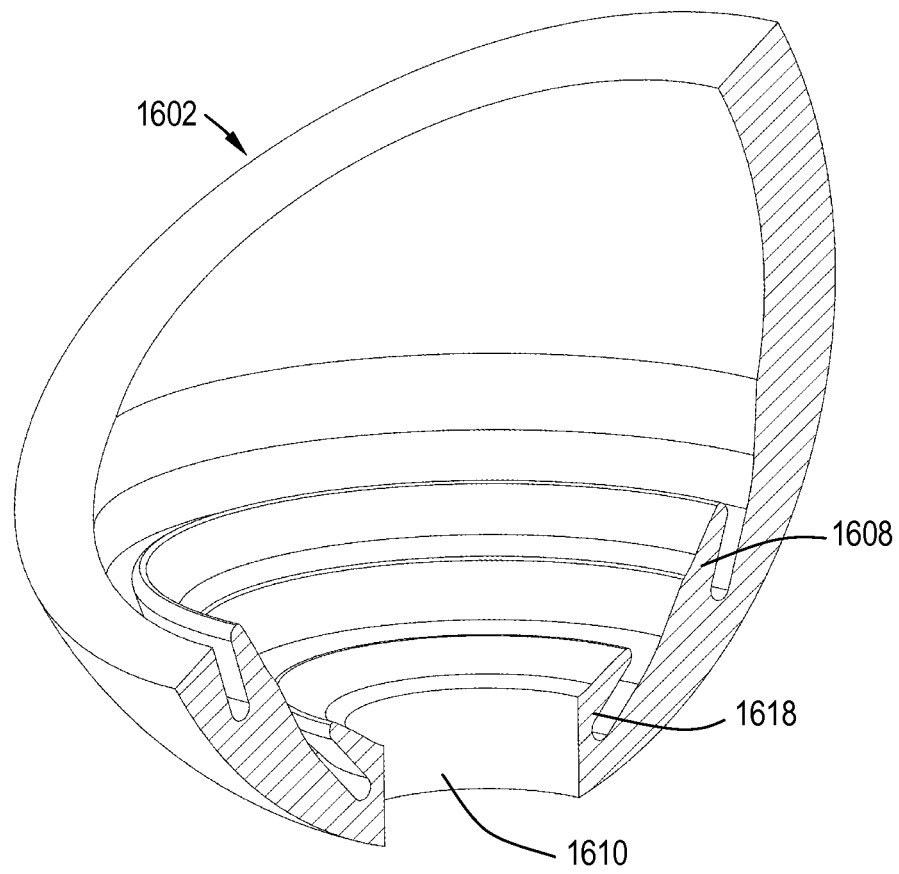


FIG. 52

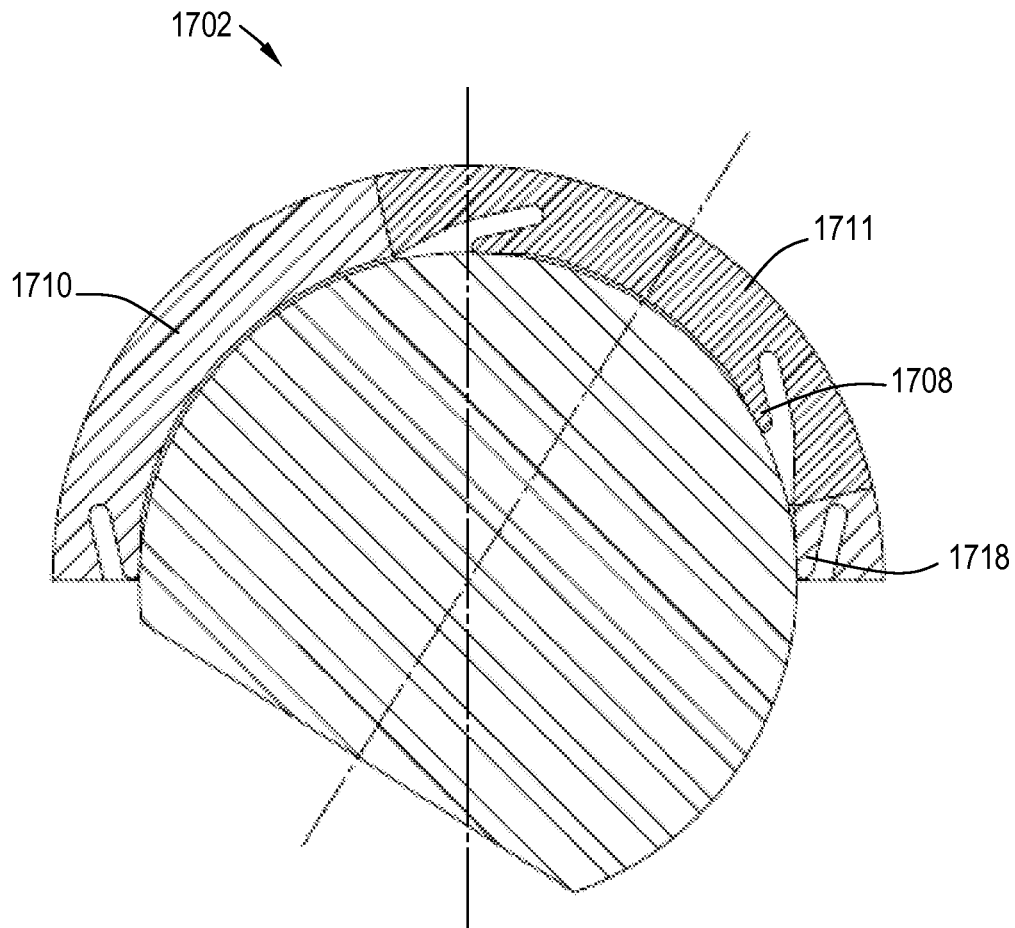


FIG. 53

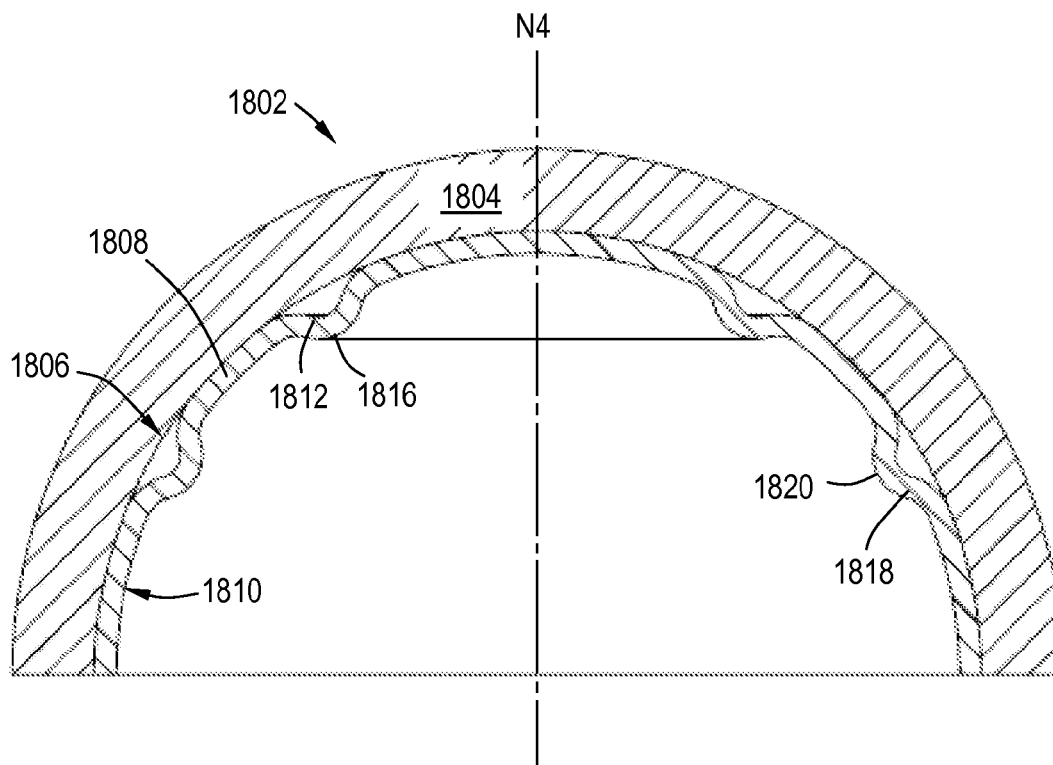


FIG. 54



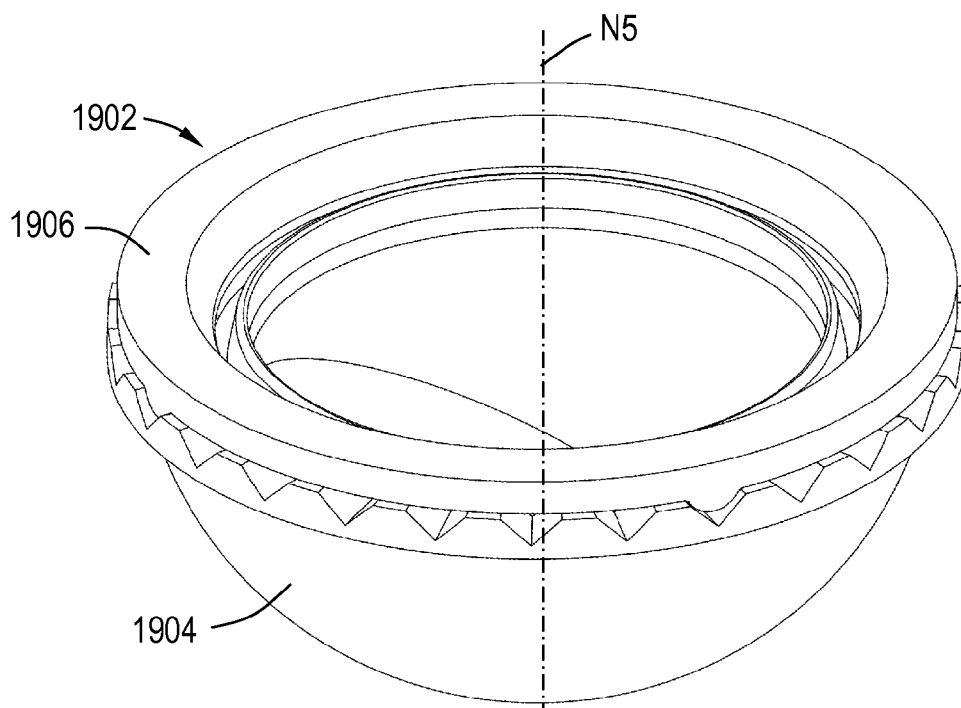


FIG. 55

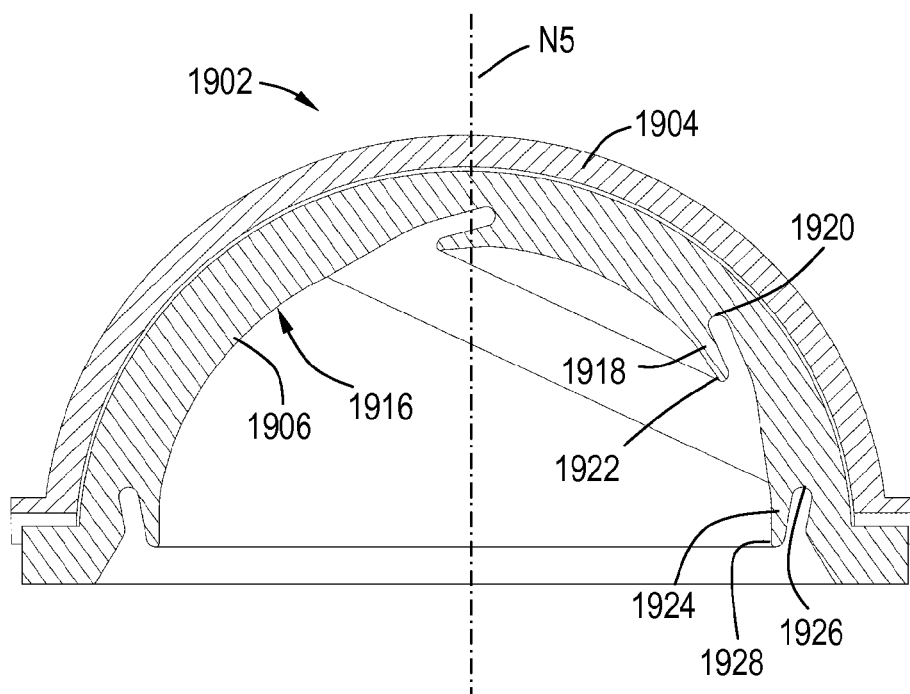


FIG. 56

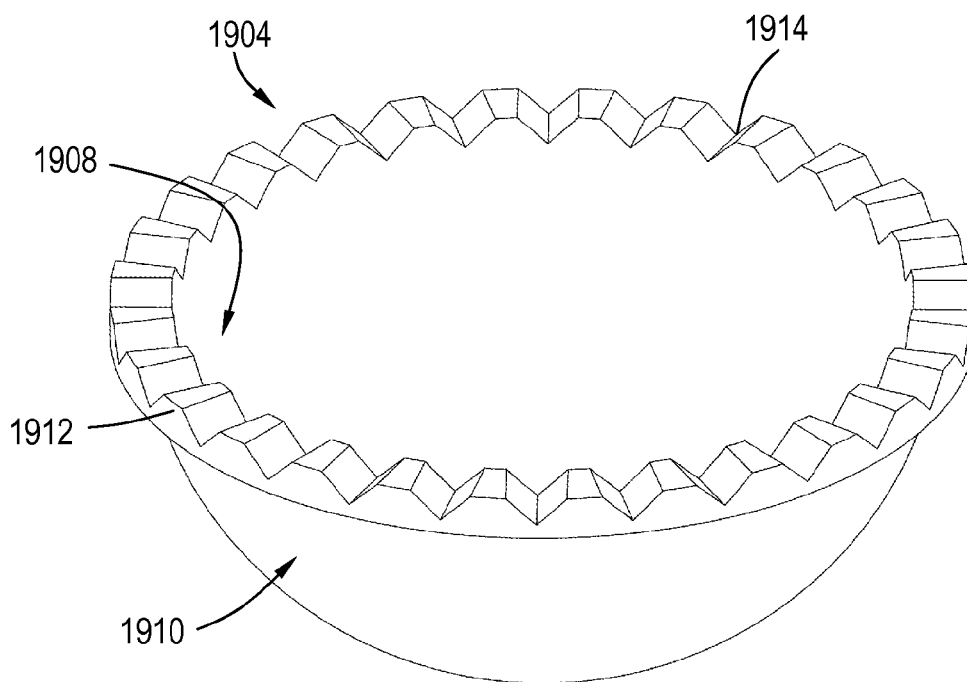


FIG. 57

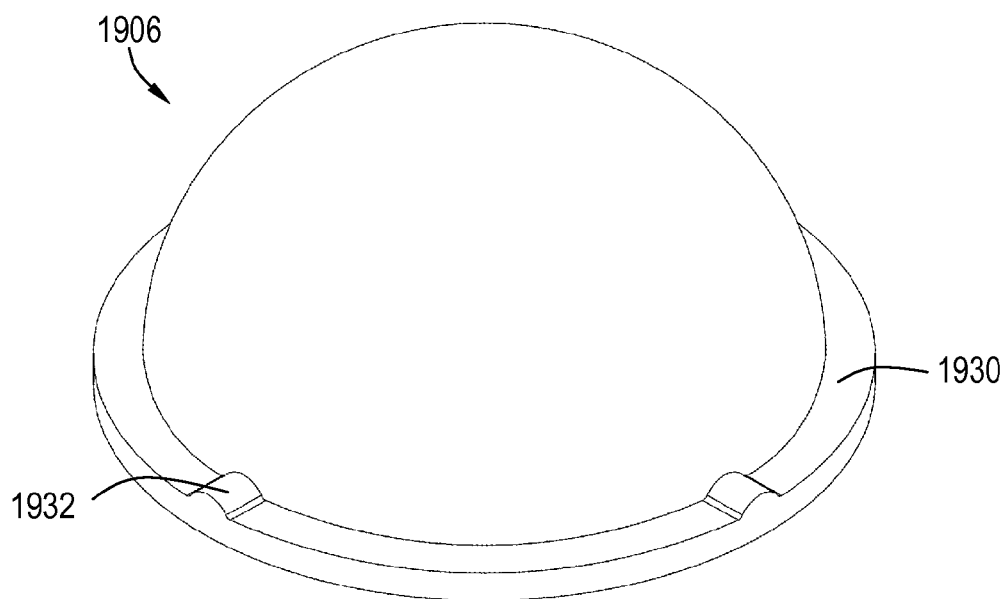


FIG. 58

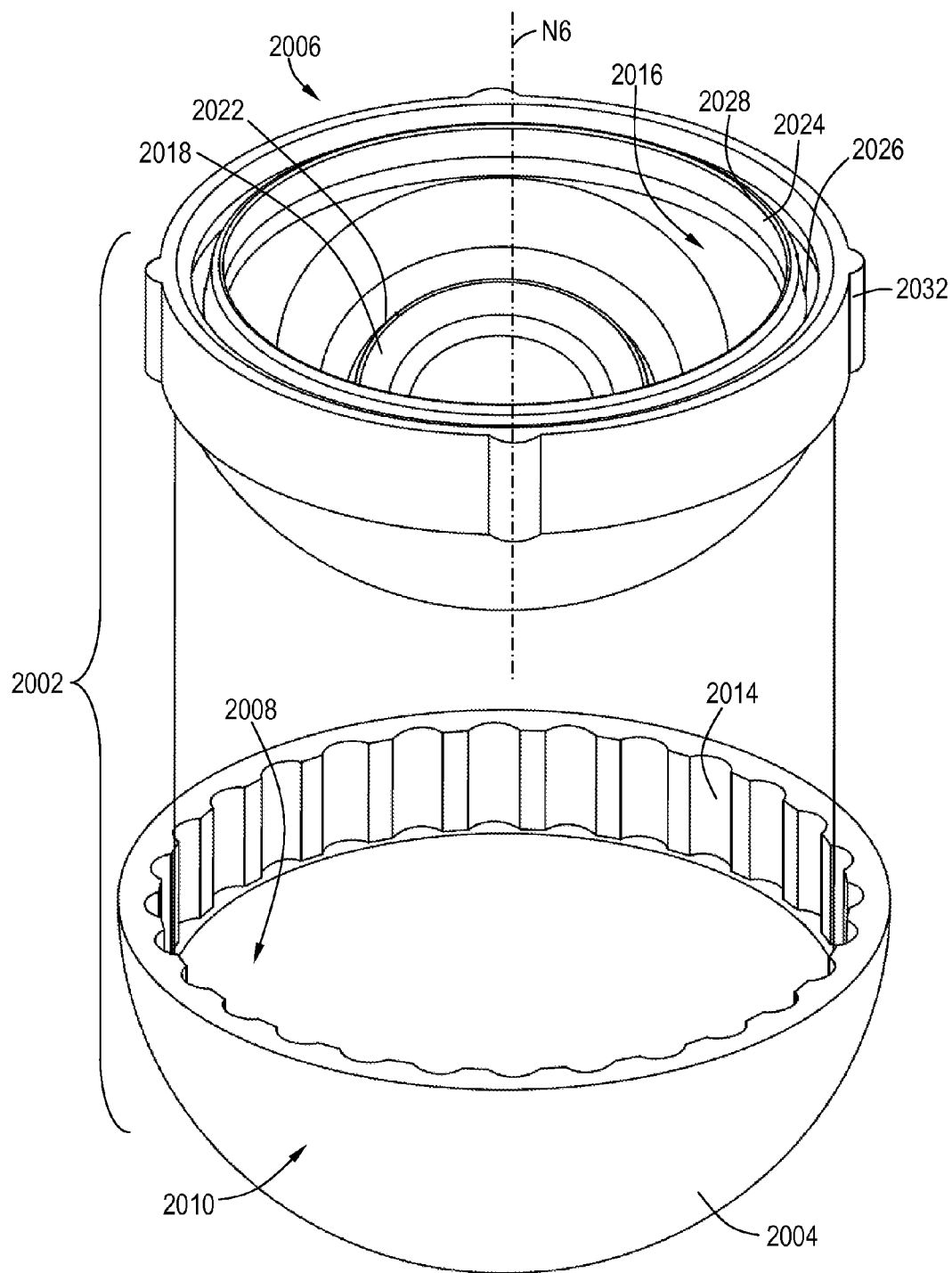


FIG. 59

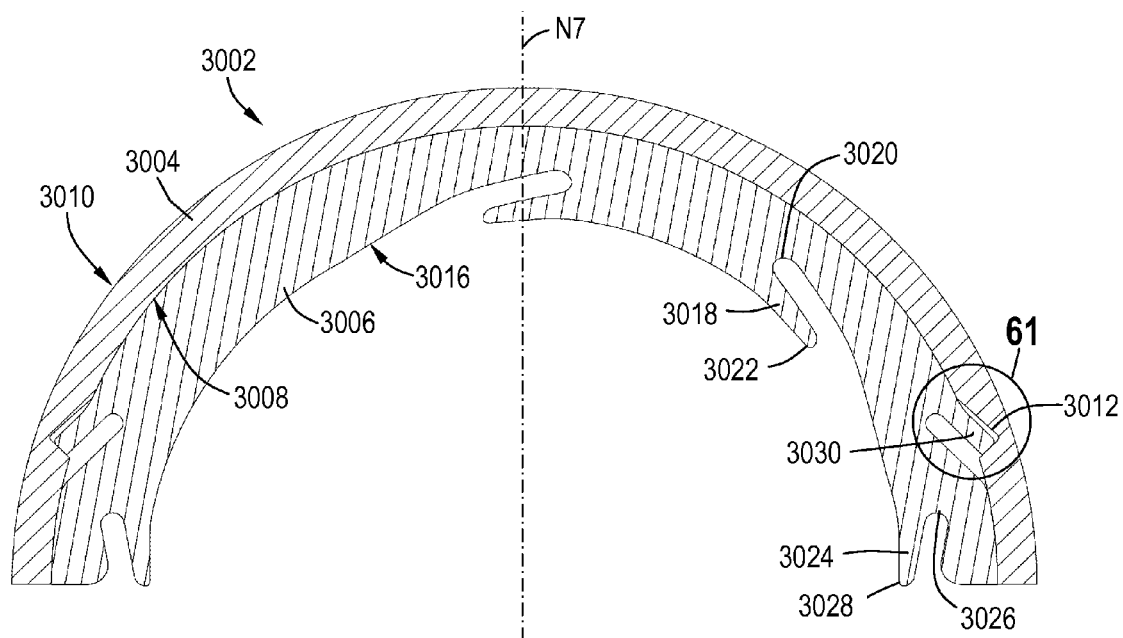


FIG. 60

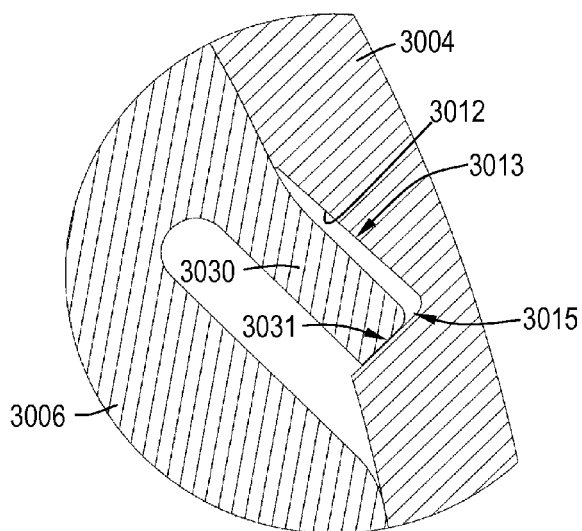


FIG. 61

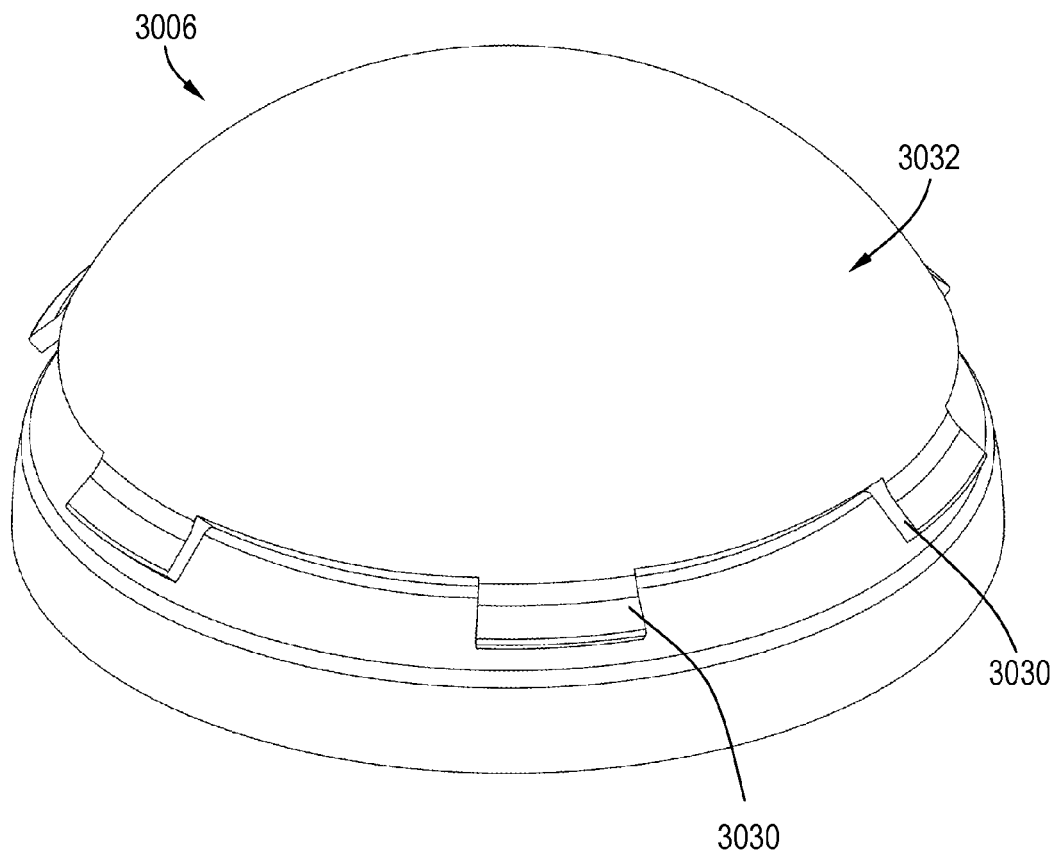


FIG. 62

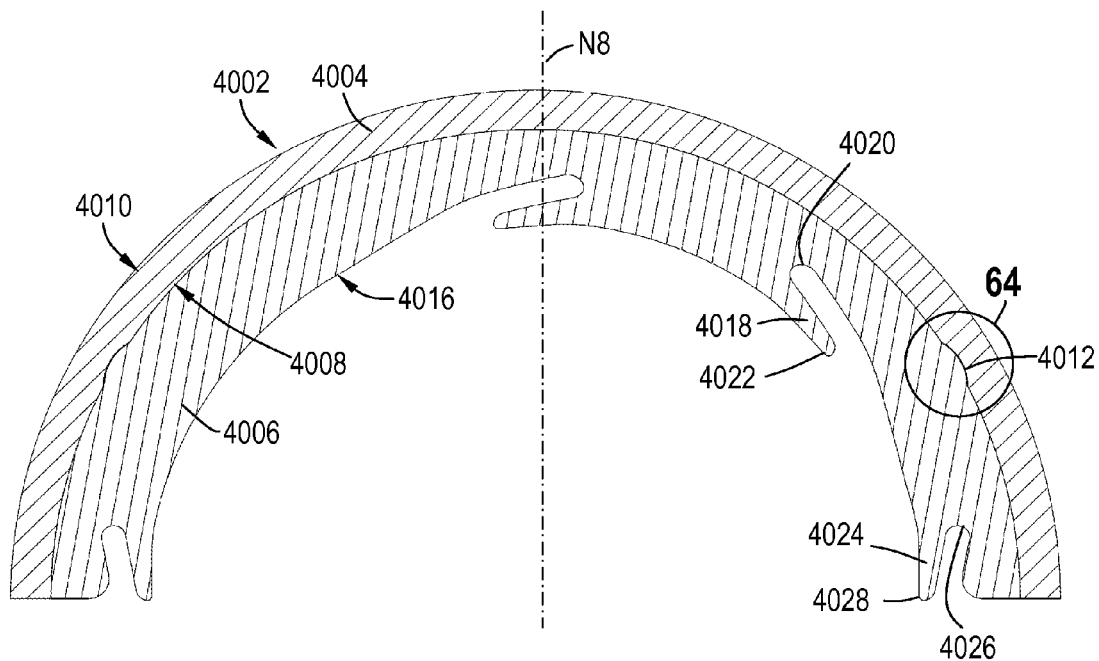


FIG. 63

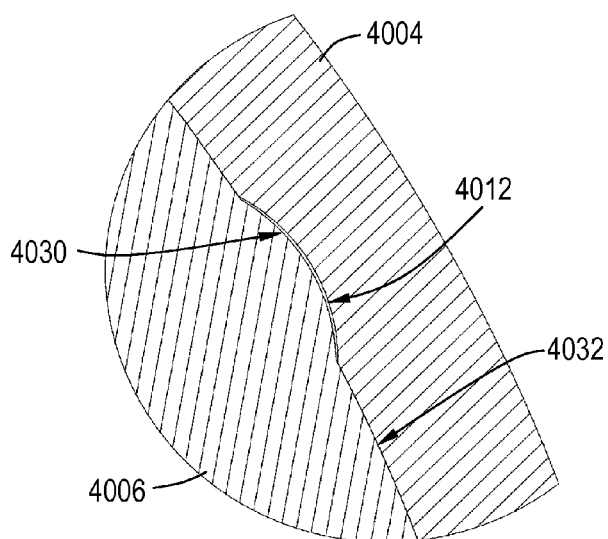


FIG. 64

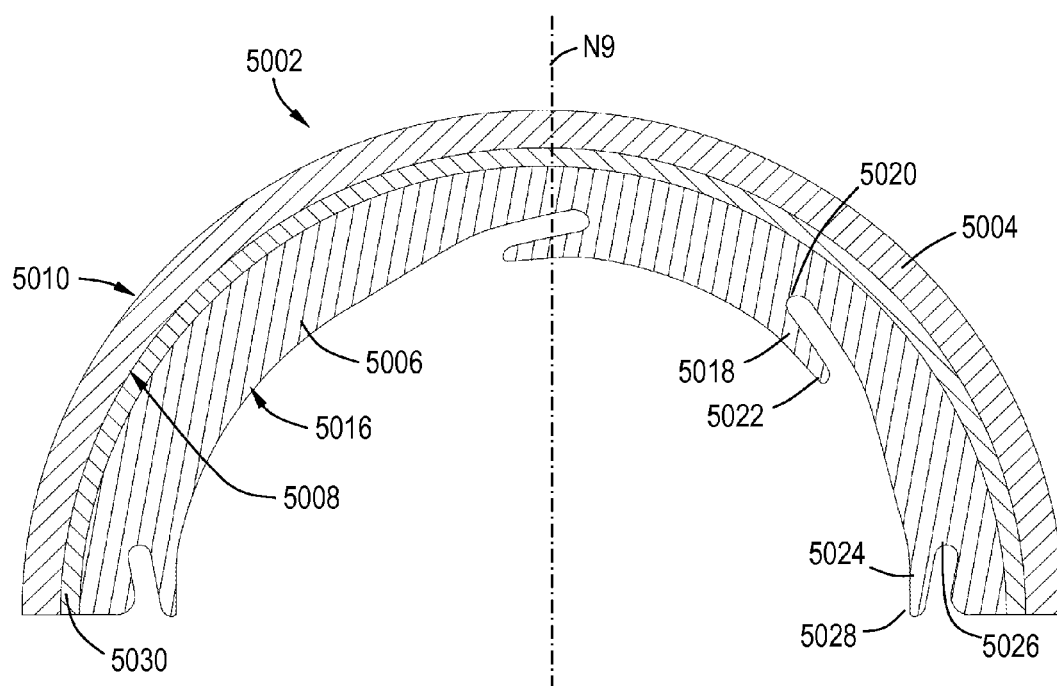


FIG. 65

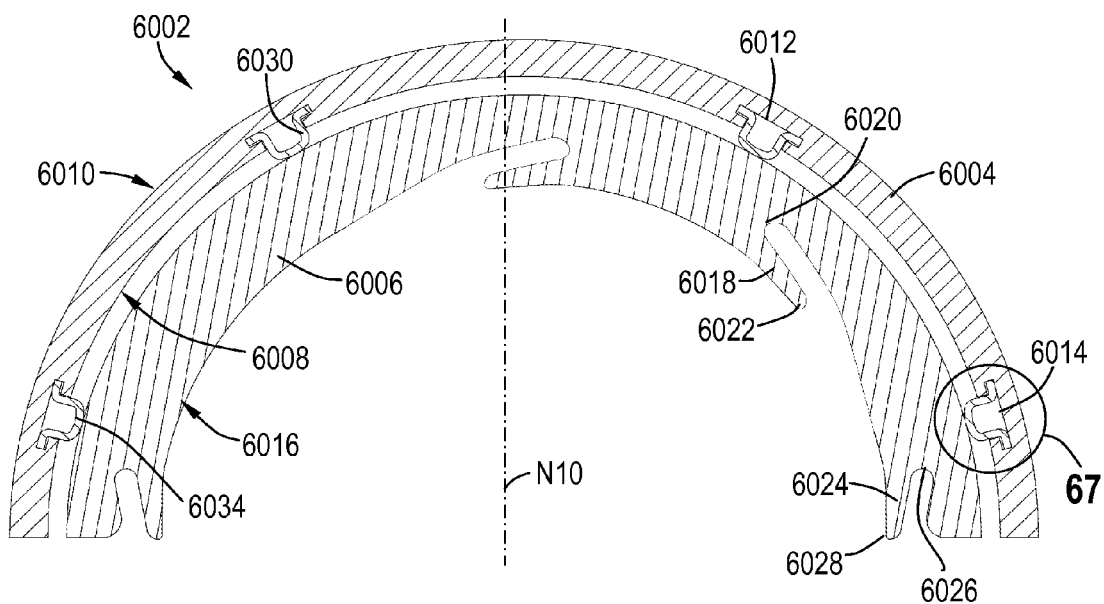


FIG. 66

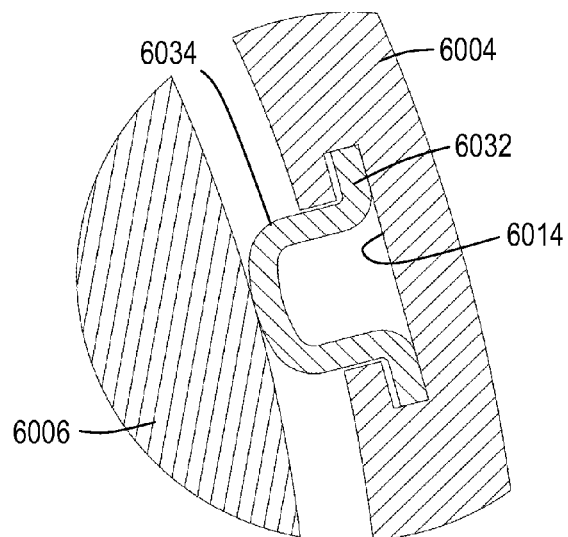


FIG. 67



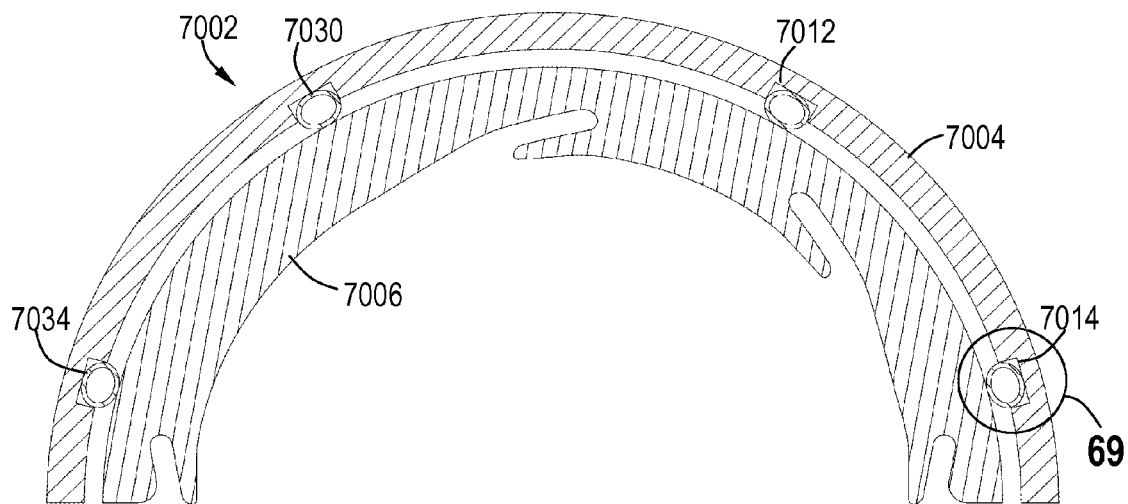


FIG. 68

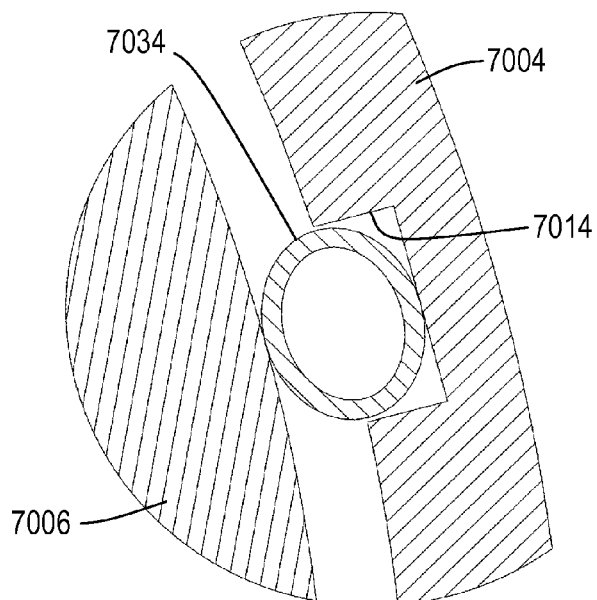


FIG. 69

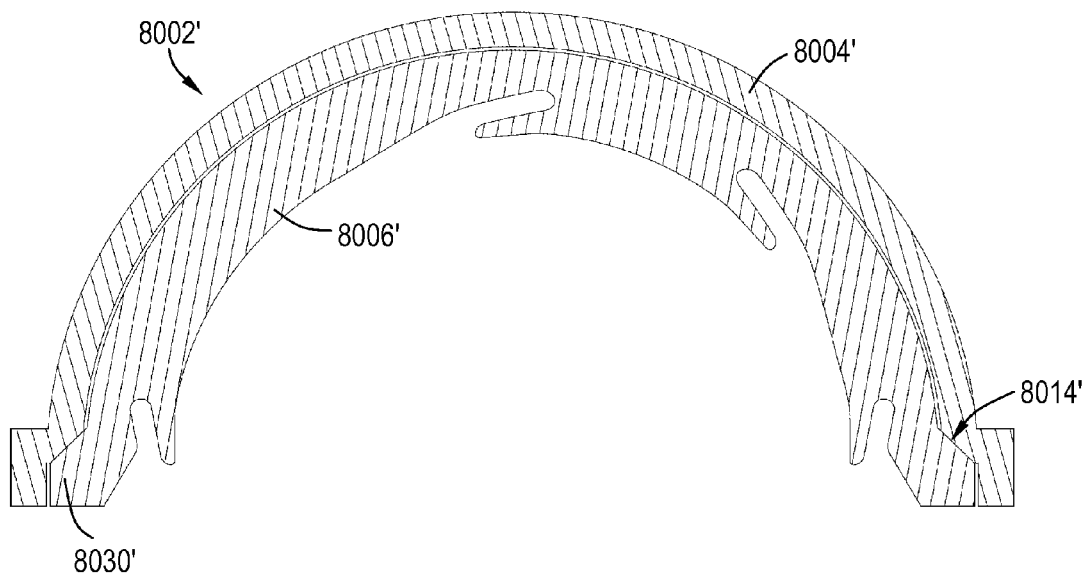
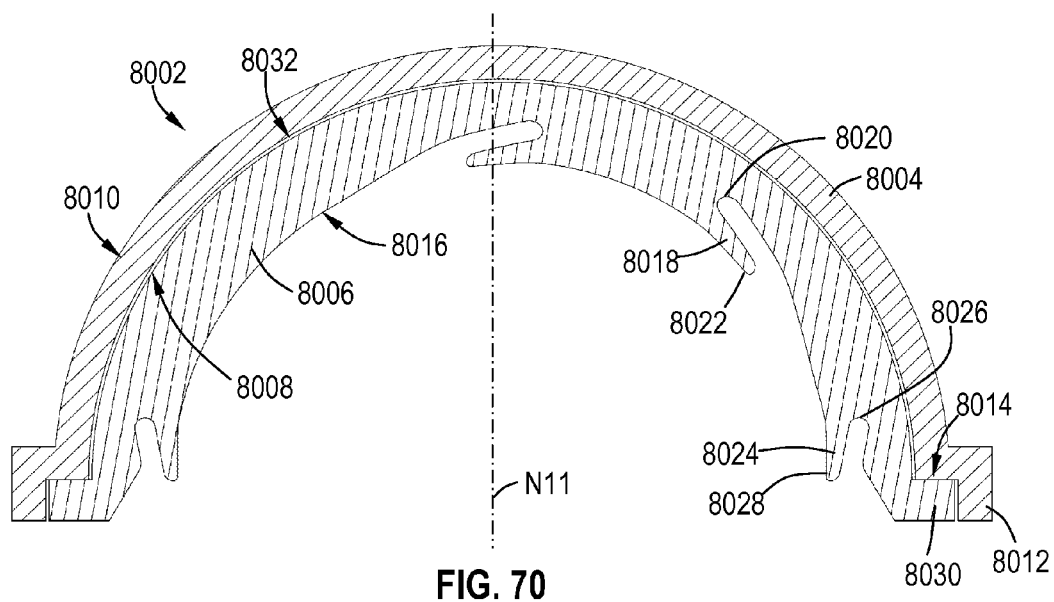


FIG. 71

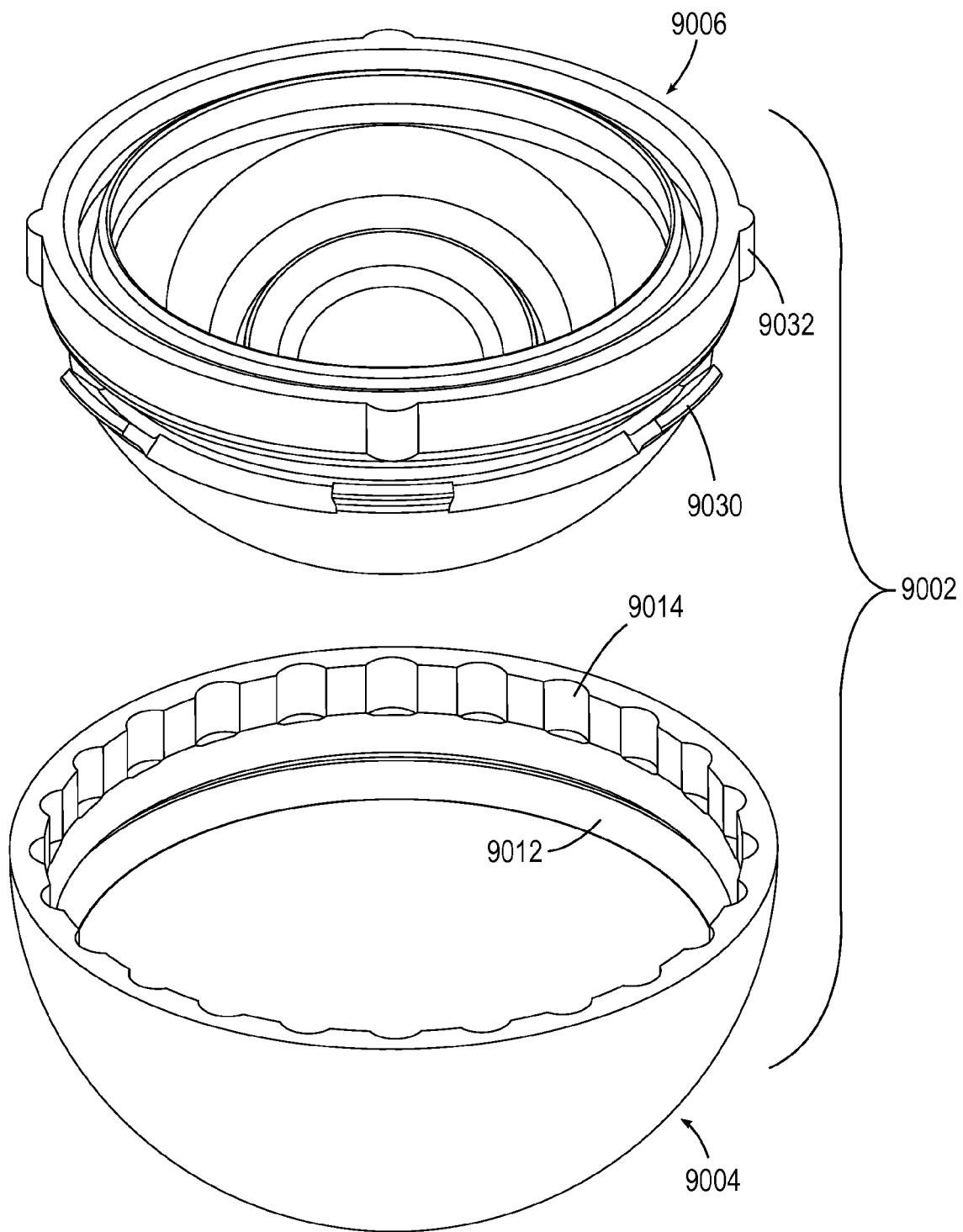


FIG. 72

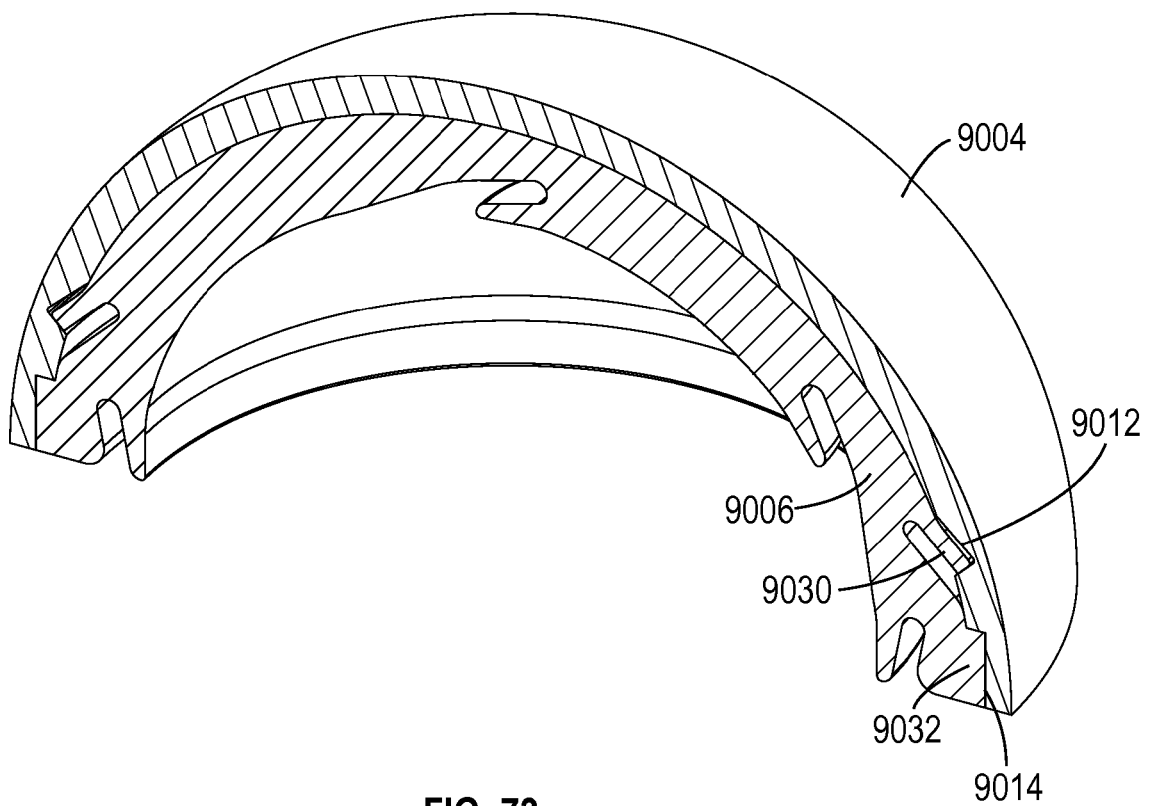


FIG. 73

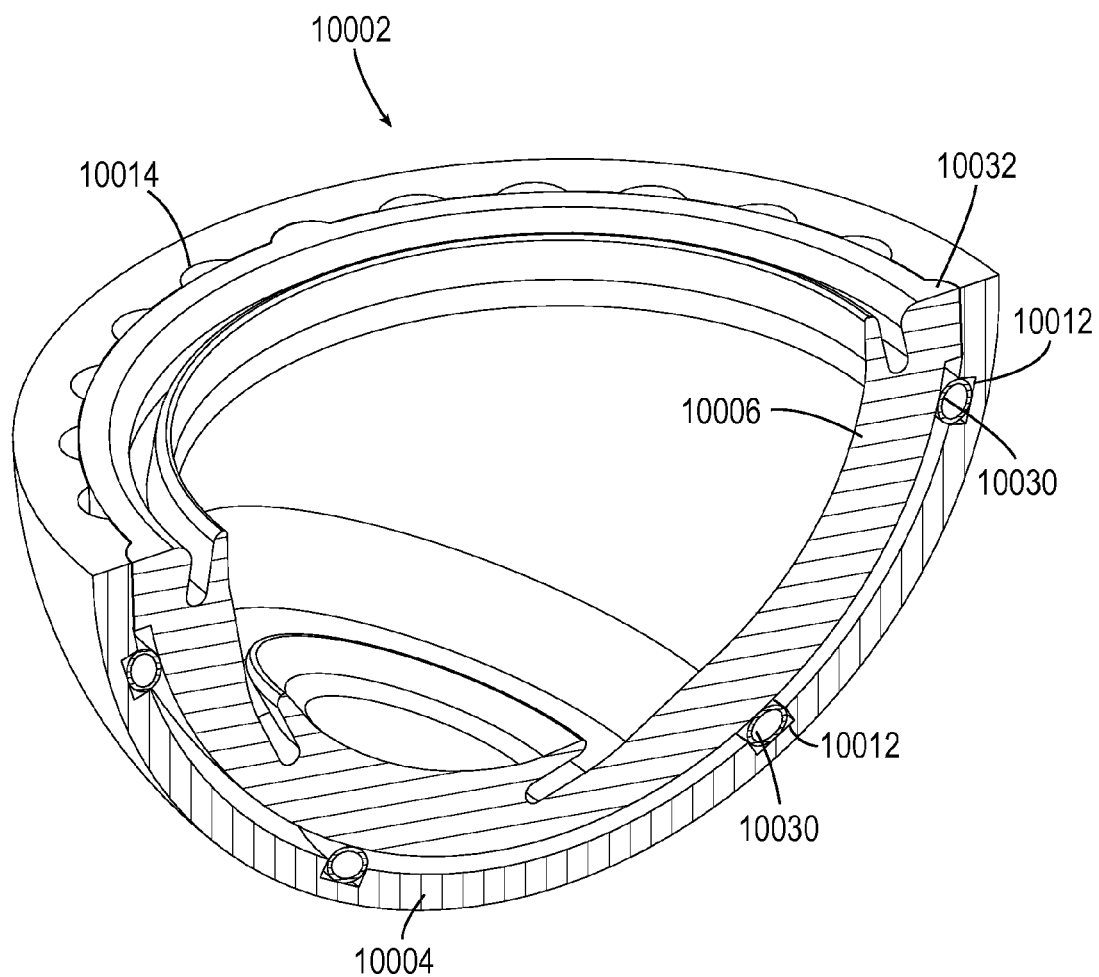


FIG. 74

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## PROSTHETIC JOINT ASSEMBLY AND PROSTHETIC JOINT MEMBER

### BACKGROUND OF THE INVENTION

This invention relates generally to medical implants, and more particularly to prosthetic joints having conformal geometries and wear resistant properties.

Medical implants, such as knee, hip, and spine orthopedic replacement joints and other joints and implants have previously consisted primarily of a hard metal motion element that engages a polymer contact pad. This has usually been a high density high wear resistant polymer, for example Ultra-High Molecular Weight Polyethylene (UHMWPE), or other resilient material. The problem with this type of configuration is the polymer eventually begins to degrade due to the caustic nature of blood, the high impact load, and high number of load cycles. As the resilient member degrades, pieces of polymer may be liberated into the joint area, often causing accelerated wear, implant damage, and tissue inflammation and harm.

It is desirable to employ a design using a hard member on a hard member (e.g. metals or ceramics), thus eliminating the polymer. Such a design is expected to have a longer service life. Extended implant life is important as it is now often required to revise or replace implants. Implant replacement is undesirable from a cost, inconvenience, patient health, and resource consumption standpoint.

Implants using two hard elements of conventional design will be, however, subject to rapid wear. First, a joint having one hard, rigid element on another will not be perfectly shaped to a nominal geometry. Such imperfections will result in points of high stress, thus causing localized wear. Furthermore, two hard elements would lack the resilient nature of a natural joint. Natural cartilage has a definite resilient property, absorbing shock and distributing periodic elevated loads. This in turn extends the life of a natural joint and reduces stress on neighboring support bone and tissue. If two rigid members are used, this ability to absorb the shock of an active lifestyle could be diminished. The rigid members would transmit the excessive shock to the implant to bone interface. Some cyclical load in these areas stimulates bone growth and strength; however, excessive loads or shock stress or impulse loading the bone-to-implant interface will result in localized bone mass loss, inflammation, and reduced support.

### BRIEF SUMMARY OF THE INVENTION

These and other shortcomings of the prior art are addressed by the present invention, which provides a prosthetic joint having wear-resistant contacting surfaces with conformal properties.

According to one aspect of the invention, a prosthetic member includes: a cup with an outer surface that is bone-implantable, the cup including a first indexing feature; an insert disposed inside the cup, the insert comprising a rigid material and including a concave interior defining a nominal surface, the interior including a cantilevered flange defined by an undercut in the insert, the flange defining a wear-resistant first contact surface which protrudes inward relative to the nominal surface, the insert including a second indexing feature; wherein the first and second indexing features engage each other so as to retain the insert in a fixed angular orientation relative to the cup.

### BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be best understood by reference to the following description taken in conjunction with the accompanying drawing figures in which:

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FIG. 1 is a cross-sectional view of a portion of a resilient contact member constructed in accordance with the present invention;

FIG. 2 is an enlarged view of the contact member of FIG. 1 in contact with a mating joint member;

FIG. 3 is a side view of a resilient contact member in contact with a mating joint member;

FIG. 4 is a cross-sectional view of a cup for an implant according to an alternate embodiment of the invention;

FIG. 5 is an enlarged view of a portion of the cup of FIG. 4;

FIG. 6 is a perspective view of a finite element model of a joint member;

FIG. 7 is a cross-sectional view of an implant joint including a flexible seal;

FIG. 8 is an enlarged view of a portion of FIG. 7;

FIG. 9 is a side view of a prosthetic joint constructed in accordance with an aspect of the present invention;

FIG. 10 is a cross-sectional view of the prosthetic joint of FIG. 9 in an unloaded condition;

FIG. 11 is a cross-sectional view of one of the members of the prosthetic joint of FIG. 9;

FIG. 12 is an enlarged view of a portion of FIG. 10;

FIG. 13 is a cross-sectional view of the prosthetic joint of FIG. 9 in a loaded condition;

FIG. 14 is an enlarged view of a portion of FIG. 13;

FIG. 15 is a cross-sectional view of an alternative joint member;

FIG. 16 is an enlarged view of a portion of FIG. 15;

FIG. 17 is a cross-sectional view of another alternative joint member;

FIG. 18 is a cross-sectional view of another alternative joint member including a filler material;

FIG. 19 is a cross-sectional view of another alternative joint member including a wiper seal;

FIG. 20 is a cross-sectional view of another alternative prosthetic joint;

FIG. 21 is a cross-sectional view of a prosthetic joint constructed in accordance with another aspect of the present invention;

FIG. 22 is a cross-sectional view of a prosthetic joint constructed in accordance with yet another aspect of the present invention; and

FIG. 23 is a perspective view of a joint member having a grooved surface.

FIG. 24 is an exploded perspective view of two mating joint members;

FIG. 25 is a top plan view of one of the joint members shown in FIG. 24;

FIG. 26 is a cross-sectional view of one of the joint members shown in FIG. 24;

FIG. 27 is a contact stress plot of the joint member shown in FIG. 26;

FIG. 28 is a perspective view of a rigid joint member used for comparison purposes;

FIG. 29 is a cross-sectional view of the joint member shown in FIG. 28; and

FIG. 30 is a contact stress plot of the joint member shown in FIG. 29;

FIG. 31 is a cross-sectional view of a prosthetic joint constructed in accordance with another aspect of the present invention;

FIG. 32 is an enlarged view of a portion of the joint shown in FIG. 31;

FIG. 33 is a cross-sectional view of a cup member of the joint shown in FIG. 31;

FIG. 34 is a greatly enlarged cross-sectional view of a portion of the joint shown in FIG. 31 in an initial condition;

FIG. 35 is a greatly enlarged cross-sectional view of a portion of the joint shown in FIG. 31 after an initial wear-in period;

FIG. 36 is a graph showing contact pressure of the joint of FIG. 31 compared to the number of operating cycles;

FIG. 37 is a cross-sectional view of a prosthetic joint constructed in accordance with another aspect of the present invention;

FIG. 38 is an enlarged view of a portion of the joint shown in FIG. 37;

FIG. 39 is a cross-sectional view of a prosthetic joint constructed in accordance with another aspect of the present invention;

FIG. 40 is a cross-sectional view of a prosthetic joint constructed in accordance with another aspect of the present invention;

FIG. 41 is a plan view of a portion of a prosthetic joint constructed in accordance with another aspect of the present invention;

FIG. 42 is a view taken along lines 42-42 of FIG. 41;

FIG. 43 is a view taken along lines 43-43 of FIG. 41;

FIG. 44 is a cross-sectional view of a prosthetic joint constructed in accordance with another aspect of the present invention;

FIG. 45 is a perspective view of the prosthetic joint of FIG. 44;

FIG. 46 is a perspective view of a prosthetic joint constructed in accordance with another aspect of the present invention;

FIG. 47 is a cross-sectional view of the prosthetic joint of FIG. 46;

FIG. 48 is a sectional perspective view of a prosthetic joint constructed in accordance with another aspect of the present invention;

FIG. 49 is an enlarged portion of the joint of FIG. 48, showing a rim configuration thereof;

FIG. 50 is a sectional perspective view showing an alternative rim configuration for use with the joint shown in FIG. 49;

FIG. 51 is a sectional perspective view showing another alternative rim configuration for use with the joint shown in FIG. 49;

FIG. 52 is a sectional perspective view of a member of a prosthetic joint with an aperture formed therein;

FIG. 53 is a cross-sectional view of a prosthetic joint showing a multi-piece construction;

FIG. 54 is a cross-sectional view of a prosthetic joint constructed in accordance with another aspect of the present invention

FIG. 55 is a perspective view of a prosthetic joint member;

FIG. 56 is a cross-sectional view of the joint member of FIG. 55;

FIG. 57 is a perspective view of a cup of the joint member of FIG. 55;

FIG. 58 is a perspective view of an insert of the joint member of FIG. 55;

FIG. 59 is an exploded perspective view of a prosthetic joint member;

FIG. 60 is a cross-sectional view of a prosthetic joint member;

FIG. 61 is an enlarged view of a portion of the joint member of FIG. 60;

FIG. 62 is a perspective view of an insert of the joint member of FIG. 60;

FIG. 63 is a cross-sectional view of a prosthetic joint member;

FIG. 64 is an enlarged view of a portion of the joint member of FIG. 63;

FIG. 65 is a cross-sectional view of a prosthetic joint member;

FIG. 66 is a cross-sectional view of a prosthetic joint member;

FIG. 67 is an enlarged view of a portion of the joint member of FIG. 66;

FIG. 68 is a cross-sectional view of a prosthetic joint member;

FIG. 69 is an enlarged view of a portion of the joint member of FIG. 68;

FIG. 70 is a cross-sectional view of a prosthetic joint member;

FIG. 71 is a cross-sectional view of a prosthetic joint member;

FIG. 72 is an exploded perspective view of a prosthetic joint;

FIG. 73 is a perspective cross-sectional view of the prosthetic joint of FIG. 72; and

FIG. 74 is a perspective cross-sectional view of a prosthetic joint.

#### DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a specialized implant contact interface (implant geometry). In this geometry, an implanted joint includes two typically hard (i.e. metal or ceramic) members; however, at least one of the members is formed such that it has the characteristics of a resilient member, such as: the ability to absorb an impact load; the ability to absorb high cycle loading; the ability to be self cleaning; and the ability to function as a hydrodynamic and/or hydrostatic bearing.

Generally, the contact resilient member is flexible enough to allow elastic deformation and avoid localized load increases, but not so flexible as to risk plastic deformation, cracking and failure. In particular, the resilient member is designed such that the stress levels therein will be below the high-cycle fatigue endurance limit. As an example, the resilient member might be only about 10% to about 20% as stiff as a comparable solid member. It is also possible to construct the resilient member geometry with a variable stiffness, i.e. having a low effective spring rate for small deflections and a higher rate as the deflections increase, to avoid failure under sudden heavy loads.

FIG. 1 illustrates an exemplary contact member 34 including a basic resilient interface geometry. The contact member 34 is representative of a portion of a medical implant and is made of one or more metals or ceramics (for example, partially stabilized Zirconia). It may be coated as described below. The geometry includes a lead-in shape, Z1 and Z2, a contact shape, Z3 and Z4, a lead-out shape, Z5 and Z6, and a relieved shape, Z7. It may be desired to vary the cross-sectional thickness to achieve a desired mechanical stiffness to substrate resilience characteristic. The presence of the relieved region Z7 introduces flexibility into the contact member 34, reduces the potential for concentrated point contact with a mating curved member, and provides a reservoir for a working fluid.

The Z7 region may be local to the contact member 34 or may be one of several. In any case, it may contain a means of providing fluid pressure to the internal contact cavity to produce a hydrostatic interface. A passive (powered by the regular motion of the patient) or active (powered by micro com-

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ponents and a dedicated subsystem) pumping means and optional filtration may be employed to provide the desired fluid interaction.

A hydrodynamic interface is desirable as, by definition, it means the contact member **34** is not actually touching the mating joint member. The lead-in and lead-out shapes **Z1**, **Z2**, **Z5**, **Z6** are configured to generate a shear stress in the working fluid so as to create the fluid “wedge” of a hydrodynamic support.

FIG. 2 shows a closer view of the contact member **34**. It may be desirable to make the contact radius (**Z3** and **Z4**) larger or smaller, depending on the application requirement and flexural requirement. For example, FIG. 3 illustrates the contact member **34** in contact with a mating joint member **38** having a substantially larger radius than the contact member **34**. The radius ratio between the two joint members is not particularly critical, so long as one of the members exhibits the resilient properties described herein.

The contact member **34** includes an osseointegration surface “S”, which is a surface designed to be infiltrated by bone growth to improve the connection between the implant and the bone. Osseointegration surfaces may be made from materials such as TRABECULAR METAL, textured metal, or sintered or extruded implant integration textures. TRABECULAR METAL is an open metal structure with a high porosity (e.g. about 80%) and is available from Zimmer, Inc., Warsaw, Ind. 46580 USA.

FIGS. 4 and 5 illustrate a cup **48** of metal or ceramic with two integrally-formed contact rings **50**. More contact rings may be added if needed. As shown in FIG. 5, the volume behind the contact rings **50** may be relieved. This relieved area **52** may be shaped so as to produce a desired balance between resilience and stiffness. A varying cross-section geometry defined by varying inner and outer spline shapes may be desired. In other words, a constant thickness is not required. A material such as a gel or non-Newtonian fluid (not shown) may be disposed in the relieved area **52** to modify the stiffness and damping characteristics of the contact rings **50** as needed for a particular application. The cup **48** could be used as a stand-alone portion of a joint, or it could be positioned as a liner within a conventional liner. The contact ring **50** is shown under load in FIG. 6, which depicts contour lines of highest compressive stress at “C1”. This is the portion of the contact ring **50** that would be expected to undergo bending first. The bearing interface portion of the resilient contact member could be constructed as a bridge cross-section supported on both sides as shown or as a cantilevered cross-section depending on the desired static and dynamic characteristics.

FIGS. 7 and 8 illustrate an implant **56** of rigid material which includes a wiper seal **58**. The wiper seal **58** keeps particles out of the contact area (seal void) **60** of the implant **58**, and working fluid (natural or synthetic) in. The seal geometry is intended to be representative and a variety of seal characteristics may be employed; such as a single lip seal, a double or multiple lip seal, a pad or wiper seal made from a variety of material options. Different seal mounting options may be used, for example a lobe in a shaped groove as shown in FIGS. 7 and 8, a retaining ring or clamp, or an adhesive. The wiper seal **58** may also be integrated into the contact face of the interface zone.

It may be desirable to create a return passage **62** from the seal void region **60** back into the internal zone **64** in order to stabilize the pressure between the two and to allow for retention of the internal zone fluid if desired. This is especially relevant when the hydrostatic configuration is considered.

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FIGS. 9-14 illustrate a prosthetic joint **100** comprising first and second members **102** and **104**. The illustrated prosthetic joint **100** is particularly adapted for a spinal application, but it will be understood that the principles described herein may be applied to any type of prosthetic joint. Both of the members **102** and **104** may be bone-implantable, meaning they include osseointegration surfaces, labeled “S”, which are surfaces designed to be infiltrated by bone growth to improve the connection between the implant and the bone. Osseointegration surfaces may be made from materials such as TRABECULAR METAL, textured metal, or sintered or extruded implant integration textures, as described above. As shown in FIG. 10, a central axis “A” passes through the centers of the first and second members **102** and **104** and is generally representative of the direction in which external loads are applied to the joint **100** in use. In the illustrated examples, the first and second joint members are bodies of revolution about this axis, but the principles of the present invention also extend to shapes that are not bodies of revolution.

The first member **102** includes a body **106** with a perimeter flange **116** extending in a generally radially outward direction at one end. Optionally, a disk-like base **108** may be disposed at the end of the body **106** opposite the flange **116**, in which case a circumferential gap **111** will be defined between the base **106** and the flange **116**. The first member **102** is constructed from a rigid material. As used here, the term “rigid” refers to a material which has a high stiffness or modulus of elasticity. Nonlimiting examples of rigid materials having appropriate stiffness for the purpose of the present invention include stainless steels, cobalt-chrome alloys, titanium, aluminum, and ceramics. By way of further example, materials such as polymers would generally not be considered “rigid” for the purposes of the present invention. Generally, a rigid material should have a modulus of elasticity of about  $0.5 \times 10^6$  psi or greater. Collectively, one end of the body **106** and the flange **116** define a wear-resistant, concave first contact surface **118**. As used herein, the term “wear-resistant” refers to a material which is resistant to surface material loss when placed under load. Generally the wear rate should be no more than about  $0.5 \mu\text{m}$  ( $0.000020$  in.) to about  $1.0 \mu\text{m}$  ( $0.000040$  in.) per million cycles when tested in accordance with ASTM Guide F2423. As a point of reference, it is noted that any of the natural joints in a human body can easily experience one million operating cycles per year. Nonlimiting examples of wear-resistant materials include solid metals and ceramics. Known coatings such as titanium nitride, chrome plating, carbon thin films, and/or diamond-like carbon coatings may be used as a face layer to impart wear resistance to the first contact surface **118**. Optionally, the first contact surface **118** could comprise a substantially thicker face layer (not shown) of a wear-resistant material such as ultra-high molecular weight (UHMW) polyethylene.

The first contact surface **118** includes a protruding peripheral rim **120** (see FIG. 11), and a recessed central portion **122**, which may also be considered a “pocket” or a “relief”. As used herein, the term “recessed” as applied to the central portion **122** means that the central portion **122** lies outside of the nominal exterior surface of the second member **104** when the joint **100** is assembled. The terms “recessed” and “protruding” as used herein are opposite in meaning to one another. For example, the peripheral rim **120** protrudes relative to a nominal surface defined by the central portion **122**, and the central portion **122** is recessed relative to the rim **120**. In one configuration, shown in FIGS. 9-14, and best seen in FIG. 11, the rim **120** is concave, with the radius of curvature being quite high, such that the cross-sectional shape of the surface of the rim **120** approaches a straight line. FIGS. 15



and 16 show another configuration of a joint member 102' with a flange 116' in which the rim 120' has a convex-curved cross-sectional shape. The cross-sectional shape of the rim may be flat or curved as necessary to suit a particular application.

The annular configuration of first contact surface 118 with the protruding rim 120 results in a configuration which permits only pivoting and rotational motion, and is statically and dynamically determinate for the life of the joint 100. In contrast, prior art designs employing mating spherical shapes, even very accurate shapes, quickly reach a statically and dynamically indeterminate condition after use and wear. This condition accelerates wear, contributes to the fretting corrosion wear mechanism, and permits undesired lateral translation between the joint members.

The second member 104 is also made from a rigid material and has a wear-resistant, convex second contact surface 124. The first and second contact surfaces 118 and 124 bear directly against each other so as to transfer axial and lateral loads from one member to the other while allowing pivoting motion between the two members 102 and 104.

Nominally the first and second members 102 and 104 define a "ring" or "band" contact interface therebetween. In practice it is impossible to achieve surface profiles completely free of minor imperfections and variations. If the first and second members 102 and 104 were both completely rigid, this would cause high Hertzian contact stresses and rapid wear. Accordingly, an important feature of the illustrated joint 100 is that the flange 116 (and thus the first contact surface 118) of the first member 102 is conformable to the second contact surface 124 when the joint is placed under load.

FIGS. 10 and 12 show a cross-sectional view of the flange 116 in an unloaded condition or free shape. It can be seen that the distal end of the rim 120 contacts the second contact surface 124, while the inboard end of the rim 120 (i.e. near where the flange 116 joins the body 106) does not. FIGS. 13 and 14 show the flange 116 in a deflected position or loaded shape, where substantially the entire section width of the rim 120 contacts the second contact surface 124, resulting in a substantially increased contact surface area between the two members 102 and 104, relative to the free shape. The rim 120' of the joint member 102' (see FIG. 16) is similarly conformable; however, given the curved cross-sectional shape, the total amount of surface contact area remains substantially constant in both loaded and unloaded conditions, with the rim 120' undergoing a "rolling" or "rocking" motion as the loading changes.

The conformable nature of the flange 116 is explained in more detail with reference to FIGS. 24 through 30. As noted above, the first member 102 has a flange 116 and a concave first contact surface 118. The second member 104 has a convex second contact surface 124. When assembled and in use the joint 100 is subject, among other loads, to axial loading in the direction of the arrows labeled "F" in FIG. 24 (i.e. along axis "A" of FIG. 10). As previously stated, it is impossible in practice for either of the contact surfaces 118 or 124 to be perfect surfaces (i.e. a perfect sphere or other curve or collection of curves). It is believed that in most cases that a defect such as a protrusion from the nominal contact surface of just 0.00127 mm (0.00005 in.), that is, 50 millionths of an inch, or larger, would be sufficient to cause fretting corrosion and failure of a metal-on-metal joint constructed to prior art standards. A defect may include a variance from a nominal surface shape as well as a discontinuity in the contact surface. Defects may arise through a variety of sources such as manufacturing, installation, and/or operating loads in the implanted joint.

FIG. 25 shows the second member 104 which in this particular example varies from a nominal shape in that it is elliptical rather than circular in plan view. The elliptical shape is grossly exaggerated for illustrative purposes. For reference, the dimensions of the second member 104 along the major axis labeled "X" is about 0.0064 mm (0.00025 in.) larger than its dimension along the minor axis labeled "Y". When assembled and loaded, the flange 116 conforms to the imperfect second contact surface 124 and deflects in an irregular shape. In other words, in addition to any uniform deflection which may be present, the deflected shape of the flange 116 includes one or more specific locations or portions that are deflected towards or away from the nominal free shape to a greater or lesser degree than the remainder of the flange 116. Most typically the deflected shape would be expected to be non-axisymmetric. For example, the deflection of the flange 116 at points located at approximately the three o'clock and nine o'clock positions is substantially greater than the deflection of the remainder of the flange 116. As a result, the contact stress in that portion of the first contact surface 118 is relieved. FIG. 27 is a plan view plot (the orientation of which is shown by arrow in FIG. 26) which graphically illustrates the expected contact stresses in the first contact surface 118 as determined by analytical methods. The first contour line "C2" shows that a very low level of contract stress is present around the entire perimeter of the first contact surface 118. This is because the entire first contact surface 118 is in contact with the second contact surface 124. Another contour line "C3" represents the areas of maximum contact stress corresponding to the protruding portions of the elliptical second contact surface 124.

For comparative purposes, FIGS. 28 and 29 depict a member 902 constructed according to prior art principles. The member 902 has a contact surface 918 with an identical profile and dimensions of the first contact surface 118 of the first member 102. However, consistent with the prior art, the member 902 has a massive body 920 behind the entire contact surface 918, rendering the entire member 902 substantially rigid. FIG. 30 graphically illustrates the expected contact stresses in the contact surface 918 as determined by analytical methods, when the member 902 is assembled and placed in contact with the second member 104, using the same applied load as depicted in FIG. 27. Because of the rigidity of the member 902, a "bridging" effect is present wherein contact between the contact surfaces (one of which is circular in plan view, and the other of which is elliptical) effectively occurs at only two points, located at approximately the three o'clock and nine o'clock positions. A first contour line "C4" shows two discrete areas where the lowest level of contract stress is present. These lines are not contiguous because there is no contact in the remaining area of the contact surfaces (for example at the six o'clock and twelve o'clock positions). Another contour line "C5" represents the areas of maximum contact stress. Analysis shows a peak contact stress having a magnitude of two to twenty times (or more) the peak contact stress of the inventive joint as shown in FIG. 27.

To achieve this controlled deflection, the flange 116 is thin enough to permit bending under working loads, but not so thin as to allow material yield or fatigue cracking. The deflection is opposed by the elasticity of the flange 116 in bending, as well as the hoop stresses in the flange 116. To achieve long life, the first member 102 is sized so that stresses in the flange 116 will be less than the endurance limit of the material, when a selected external load is applied. In this particular example, the joint 100 is intended for use between two spinal vertebrae, and the design average axial working load is in the range of about 0 N (0 lbs.) to about 1300 N (300 lbs.). These design

working loads are derived from FDA-referenced ASTM and ISO standards for spinal disc prostheses. In this example, the thickness of the flange **116**, at a root **126** where it joins the body **106** (see FIG. **12**) is about 0.4 mm (0.015 in.) to about 5.1 mm (0.200 in.), where the outside diameter of the flange **116** is about 6.4 mm (0.25 in.) to about 7.6 cm (3.0 in.).

The joint members may include multiple rims. For example, FIG. **17** illustrates a joint member **202** where the first contact surface **218** includes two protruding rims **220**, with a circumferential groove or relief area **228** therebetween. The presence of multiple rims increases the contact surface areas between the two joint members.

If present, the circumferential gap between the flange and the base of the joint member may be filled with resilient nonmetallic material to provide damping and/or additional spring restoring force to the flange. FIG. **18** illustrates a joint member **302** with a filler **304** of this type. Examples of suitable resilient materials include polymers, natural or synthetic rubbers, and the like.

As discussed above, the joint may incorporate a wiper seal. For example, FIG. **19** illustrates a joint member **402** with a resilient wiper seal **404** protruding from the rim **420** of the first contact surface **418**. The wiper seal **404** keeps particles out of the contact area (seal void), while containing working fluid (natural or synthetic). The seal geometry is intended to be representative and a variety of seal characteristics may be employed; such as a single lip seal, a double or multiple lip seal. A pad or wiper seal may be made from a variety of material options. Different seal mounting options may be used, for example a lobe in shaped groove as shown in FIG. **18**, a retaining ring or clamp, adhesion substance. The seal may also be incorporated into the contact face of the interface zone.

The joint construction described above can be extended into a three-part configuration. For example, FIG. **20** illustrates a prosthetic joint **500** having first, second, and third members **502**, **504**, and **506**. The first and second members **502** and **504** are similar in construction to the first member **102** described above, and each includes a body **508**, an optional disk-like base **510**, and a flange **512**. The flanges **512** define wear-resistant concave first and second contact surfaces **514** and **516**, each of which includes a protruding peripheral rim, and a recessed central portion as described above. The third member **506** has a double-convex shape defining opposed wear-resistant, convex third and fourth contact surfaces **524** and **526**. The first and second **514** and **516** bear against the third and fourth contact surfaces **524** and **526**, respectively, so as to transfer axial (i.e. compression) and lateral loads between the first and second members **502** and **504** through the third member **506**, while allowing pivoting motion between the members **502**, **504**, and **506**. The first and second contact surfaces **514** and **516** are conformal to the third and fourth contact surfaces **524** and **526** as described in more detail above.

FIG. **21** illustrates an alternative prosthetic joint **600** comprising first and second members **602** and **604** constructed from rigid materials. Both of the members **602** and **604** may be bone-implantable, meaning they include osseointegration surfaces, labeled "S", as described in more detail above.

The first member **602** is hollow and includes a disk-like base **606** and a cup **608**, interconnected by a peripheral wall **610**. An interior cavity **612** is defined between the base **606** and the cup **608**. The cup **608** is constructed from a rigid material and defines a wear-resistant, concave first contact surface **614**. The first contact surface **614** includes a protruding peripheral rim **616**, and a recessed central portion **618**, which may also be considered a "pocket" or a "relief". The

rim **616** may have a conical or curved cross-sectional shape. The interior cavity **612** may be filled with resilient nonmetallic material to provide damping and/or additional spring restoring force to the flange. Examples of suitable resilient materials include polymers, natural or synthetic rubbers, and the like.

The second member **604** is constructed from a rigid material and has a wear-resistant, convex second contact surface **620**. The first and second contact surfaces **614** and **616** bear directly against each other so as to transfer axial and lateral loads from one member to the other while allowing pivoting motion between the two members **602** and **604**.

As described above with reference to the prosthetic joint **100**, the cup **606** of the first member **602** is thin enough to permit bending under working loads, but not so thin as to allow material yield or fatigue cracking. The first contact surface **614** is thus conformable to the second contact surface **620** when the prosthetic joint **600** is placed under external load.

An inverted configuration of hollow members is also possible. For example,

FIG. **22** illustrates a prosthetic joint **700** comprising first and second members **702** and **704**, both constructed of rigid materials. The first member **702** is solid and includes a wear-resistant, concave first contact surface **708**. The first contact surface **708** includes a protruding peripheral rim **710**, and a recessed central portion **712**, which may also be considered a "pocket" or a "relief".

The second member **704** is hollow and includes a dome **714** connected to a peripheral wall **716**. An interior cavity **718** is defined behind the dome **714**. The dome **714** defines a wear-resistant, convex second contact surface **720**, which is shaped and sized enough to permit bending under working loads, but not so as to allow material yield or fatigue cracking. The second contact surface **720** is thus conformable to the first contact surface **708** when the prosthetic joint **700** is placed under external load.

The first and second contact surfaces **708** and **720** bear directly against each other so as to transfer axial and lateral loads from one member to the other while allowing pivoting motion between the two members **702** and **704**.

Any of the contact surfaces described above may be provided with one or more grooves formed therein to facilitate flow of fluid or debris. For example, FIG. **23** illustrates a joint member **800** including a concave contact surface **802**. The contact surface **802** includes a circular groove **804**, and plurality of generally radially-extending grooves **806** which terminate at the center of the contact surface **802** and intersect the circular groove **804**.

FIGS. **31-33** illustrate an alternative prosthetic joint **1000** comprising first and second members **1002** and **1004**. The illustrated prosthetic joint **1000** is particularly adapted for a ball-and-socket joint application such as is found in a human hip joint (i.e. the acetabulofemoral joint) or shoulder joint (i.e. the glenohumeral joint), but it will be understood that the principles described herein may be applied to any type of prosthetic joint. Both of the members **1002** and **1004** may be bone-implantable, meaning they include osseointegration surfaces, labeled "S", which are surfaces designed to be infiltrated by bone growth to improve the connection between the implant and the bone. Osseointegration surfaces may be made from materials such as TRABECULAR METAL, textured metal, or sintered or extruded implant integration textures, as described above. As shown in FIG. **31**, a nominal central axis "A" passes through the centers of the first and second members **1002** and **1004**. In the illustrated examples, the first and second joint members **1002** and **1004** are bodies of revolution

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about this axis, but the principles of the present invention also extend to non-axisymmetric shapes.

The first member **1002** is constructed from a rigid material as described above. The first member **1002** is concave and may generally be thought of as a “cup”, although it need not have any particular degree of curvature. Its interior defines a nominal cup surface **1006** shown by the dashed line in FIG. **33**. The interior includes an annular first flange **1008** which is located relatively near an apex **1010** of the first member **1002** and which extends in a generally radial direction relative to the axis A. The first flange **1008** is defined in part by an undercut groove **1012** formed in the first member **1002**. A ramped surface **1014** forms a transition from the groove **1012** to the nominal cup surface **1006**. The first flange **1008** includes a protruding first contact rim **1016**. As used herein, the term “protruding” as applied to the first contact rim **1016** means that the first contact rim **1016** lies inside of the nominal cup surface **1006** when the joint **1000** is assembled. The first contact rim **1016** may have a curved or toroidal cross-sectional shape.

The interior also includes an annular second flange **1018** which is located at or near an outer peripheral edge **1020** of the first member **1002** and which extends in a generally axial direction relative to the axis A. The second flange **1018** is defined in part by an undercut groove **1022** formed in the first member **1002**. The second flange **1018** includes a protruding second contact rim **1024**. As used herein, the term “protruding” as applied to the second contact rim **1024** means that the second contact rim **1024** lies inside of the nominal cup surface **1006** when the joint **1000** is assembled. The second contact rim **1024** may have a curved or toroidal cross-sectional shape. Depending on the particular application, joint **1000** may include more than two flanges defining more than two contact rims.

In the illustrated example, the first member **1002** includes a face layer **1026** of a known coating such as titanium nitride, chrome plating, carbon thin films, and/or diamond-like carbon coatings, and/or a another substantially thicker wear-resistant material such as ultra-high molecular weight (UHMW) polyethylene. This face layer **1026** is used to impart wear resistance, as described above. The face layer **1026** may be extraordinarily thin. In this particular example, its as-applied thickness is about 0.0041 mm (0.00016 in.), or 160 millionths of an inch thick. The face layer **1026** is applied at a substantially uniform thickness over the surface profile which is defined by machined or formed features of the substrate. Alternatively, and especially if a much thicker face layer were used, the face layer could be profiled so as to define both the nominal cup surface **1006** and the first and second contact rims **1016** and **1024**.

The second member **1004** is also made from a rigid material and has a wear-resistant, convex contact surface **1028**. In the specific example illustrated, the second member **1004** includes a face layer **1030** of a known coating such as titanium nitride, chrome plating, carbon thin films, and/or diamond-like carbon coatings, and/or a another substantially thicker wear-resistant material such as ultra-high molecular weight (UHMW) polyethylene. This face layer **1030** is used to impart wear resistance, and may be quite thin, as described above. The first and second contact rims **1016** and **1024** bear directly against the contact surface **1028** so as to transfer axial and lateral loads from one member to the other while allowing pivoting motion between the two members **1002** and **1004**.

The annular configuration of contact rims **1016** and **1024** results in a joint configuration which permits only pivoting and rotational motion, and is statically and dynamically determinate for the life of the joint **1000**. In particular, the presence

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of the relatively widely-spaced contact rims **1016** and **1024**, and the peripheral positioning of the second contact rim **1024** is highly effective in resisting any translation of the first and second members **1002** and **1004** lateral to the axis A.

Nominally the first and second contact rims **1016** and **1024** define two separate “ring” or “band” contact interfaces with the contact surface **1028** of the second member **1004**. In practice it is impossible to achieve surface profiles completely free of minor imperfections and variations. If the first and second members **1002** and **1004** were both completely rigid, this would cause high Hertzian contact stresses (i.e. non-uniform contact) and rapid wear. Accordingly, an important feature of the illustrated joint **1000** is that the flanges **1008** and **1018** (and thus the contact rims **1016** and **1024**) of the first member **1002** are conformable to the contact surface **1028** when the joint **1000** is placed under load. The flanges **1008** and **1018** can conform to the imperfect contact surface **1028** and deflect in an irregular shape. In other words, in addition to any uniform deflection which may be present, the deflected shape of the flanges **1008** and **1018** can include one or more specific locations or portions that are deflected towards or away from the nominal free shape to a greater or lesser degree than the remainder of the flanges **1008** and **1018**. To achieve this controlled deflection, the flanges **1008** and **1018** are thin enough to permit bending under working loads, but not so thin as to allow material yield or fatigue cracking, or to exceed the endurance limit of the material. The deflection is opposed by the elasticity of the flanges **1008** and **1018** in bending, as well as the hoop stresses in the flanges **1008** and **1018**.

The contact rims **1016** and **1024** are designed in conjunction with the contact surface **1028** to create a wear characteristic that is constantly diminishing (similar to an asymptotic characteristic). With reference to FIG. **32**, the as-manufactured or initial curvatures (e.g. radii) of the first and second contact rims **1016** and **1024**, denoted “R” are different from the curvature (e.g. radius) of the contact surface **1028**, denoted “r”. It is noted that the direction of curvature (i.e. the convexity or second derivative shape) of the first and second contact rims **1016** and **1024** may be the same as, or opposite to, that of the contact surface **1028** upon initial manufacture. In this example they are opposite. When assembled and placed under load, the annular interface between each of the contact rims **1016** and **1024** and the contact surface **1028** will have a characteristic width denoted “W”, (effectively creating a contact band). The initial dimensions R and r are selected such that, even using highly wear-resistant surfaces or coatings, some wear takes place during an initial wear-in period of movement cycles. As a result, the contact band width W increases during the initial wear-in period. This increases contact area and therefore decreases contact stress for a given load. After the initial wear-in period (which preferably occurs before the joint is implanted), the contact band reaches a post wear-in width at which the contact stress is below a selected limit, below which the rate of wear in the contacting surfaces approaches a very low number or zero, consistent with a long life of the joint **1000**. FIG. **36** illustrates this wear characteristic, with the limit “L” depicted as a horizontal line.

FIGS. **34** and **35** are schematic views showing the initial wear-in of the surface of the contact rim **1016** at a microscopic (or nearly microscopic) level. It will be understood that these figures are greatly exaggerated for the purposes of illustration. On initial manufacture, as shown in FIG. **34**, the curvatures R and r of the contact rim **1016** and the contact surface **1028** have opposite directions. When assembled, the contact band width W is some nominal value, for example about 0.03 mm (0.001 in.), and the total thickness “T” of the face layer

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**1026** is at its as-applied value of about 0.0041 mm (0.00016 in.) for example. The action of the wear-in period described causes the face layer **1026** to wear to a shape complementary to the contact surface **1028**. After this wear-in period the curvature of the portion of the contact rim **1016** within the contact band, denoted “R”, and the curvature  $r$  of the contact surface **1028** are in the same direction, and the values of the two curvatures are substantially the same. For example, the thickness  $T$  at the location of the contact band may decrease by about 0.0004 mm (0.000014 in.), with a corresponding increase in the width of the contact band  $W$  to about 0.2 mm (0.008 in.). Analysis shows that this increase in contact band width and surface area can reduce mean contact pressure by over 80%.

The configuration of the flanges **1008** and **1018** are important in developing the constantly diminishing wear characteristics described above. In particular, the flanges **1008** and **1018** are sized and shaped so that deflections of the contact rims **1016** and **1024** under varying load are always essentially normal to their respective tangent points on the opposing contact surface **1028**, as the joint **1000** is loaded and unloaded. This ensures that the position of each of the contact bands remains constant and that the contact bands remain substantially uniform around the entire periphery of the joint **1000**.

An inverted configuration of the joint described above may be used. For example, FIGS. **37** and **38** illustrate a prosthetic joint **1100** having first and second members **1102** and **1104** which are substantially similar in general construction to the members of the joint **1000** described above in terms of materials, coatings, and so forth. However, in this joint **1100**, the concave member **1102** has a contact surface without protruding rings. The convex member **1104** has first and second flanges **1108** and **1118** which define first and second contact rims **1116** and **1124** which function in the same manner that the flanges and contact rims described above.

FIG. **39** illustrates an alternative prosthetic joint **1200** comprising first and second members **1202** and **1204**. The illustrated prosthetic joint **1200** is generally similar in construction and function to the prosthetic joint **1000** described above, and one or both of the members **1202** and **1204** may be bone-implantable as described above.

A For purposes of explanation and illustration the first member **1202** will be described relative to a “balanced centroidal axis”, labeled “N1” in FIG. **39**, passing through it. As used herein, the term “balanced centroidal axis” refers to a virtual line, parallel to local gravity (i.e. a local vertical), which passes through the geometric centroid of the first member **1202**, labeled “C”, when the first member is in a balanced position (i.e. when there is no rotation of the first member due to unbalanced mass). It is noted that, where the first member **1202** is presumed to have a uniform density, the centroid C will be co-located with its center of mass. If the first member **1202** were suspended in a balanced condition by a point “P” vertically above the centroid C the balanced centroidal axis N1 would coincide with a local vertical axis passing through the centroid C. In the case where the first member **1202** is a body of revolution, the balanced centroidal axis N1 would coincide or nearly coincide with the generating axis of the first member **1202**.

The first member **1202** is constructed from a rigid material and may generally be thought of as a “cup”, as described above. Its interior defines a nominal cup surface **1206**. The interior includes a cantilevered first flange **1208**, defined in part by an undercut groove **1212** formed in the first member **1202**. Without regard to the exact direction that the flange **1208** extends, it may be considered to be cantilevered relative

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to the remainder of the first member **1202**. In other words, when viewed in cross-section, it is a projecting structure, that is supported at one end and carries a load at the other end or along its length. A ramped surface **1214** forms a transition from the groove **1212** to the nominal cup surface **1206**. The first flange **1208** includes a protruding first contact rim **1216**. The first contact rim **1216** may have a straight, curved, or toroidal cross-sectional shape.

The first flange **1208** has an angular offset relative to the balanced centroidal axis N1. In other words, the first flange **1208** is asymmetric to the balanced centroidal axis N1. This is also referred to as a “non-axisymmetric” condition. In the particular example and view shown in FIG. **39**, the first flange **1208** is offset to the right side of the figure. The angular offset or asymmetric position allows the functional characteristics of the first flange **1208** to be tailored to specific operating conditions encountered by the prosthetic joint **1200**. For example, the angular offset may be selected so that the first flange is aligned with an expected primary load vector.

The interior also includes a cantilevered second flange **1218** which is defined in part by an undercut groove **1222** formed in the first member **1202**. The second flange **1218** includes a protruding second contact rim **1224**. The second contact rim **1224** may have a straight, curved, or toroidal cross-sectional shape.

The second member **1204** is also made from a rigid material and has a wear-resistant, convex contact surface **1228**. The first and second contact rims **1216** and **1224** bear directly against the contact surface **1228** so as to transfer axial and lateral loads from one member to the other while allowing pivoting motion between the two members **1202** and **1204**. The annular configuration of contact rims **1216** and **1224** results in a joint configuration which permits only pivoting and rotational motion, and is statically and dynamically determinate for the life of the joint **1200**.

Nominally the first and second contact rims **1216** and **1224** define two separate “ring” or “band” contact interfaces with the contact surface **1228** of the second member **1204**. The flanges **1208** and **1218** (and thus the contact rims **1216** and **1224**) of the first member **1202** are conformable to the contact surface **1228** when the joint **1200** is placed under load. The flanges **1208** and **1218** can conform to the imperfect contact surface **1228** and deflect in an irregular shape, in the manner described above for the joint **1200**.

The facing surfaces of either or both of the first and second members **1202** and **1204** may include a face layer of a known coating such as titanium nitride, chrome plating, carbon thin films, and/or diamond-like carbon coatings, and/or a another substantially thicker wear-resistant material such as ultra-high molecular weight (UHMW) polyethylene. This face layer is used to impart wear resistance, as described above.

Depending on the specific application, the second flange **1218** may have an angular offset like the first flange **1208**. For example, FIG. **40** illustrates a prosthetic joint **1200'** substantially similar in construction to the prosthetic joint **1200**, with first and second members **1202'** and **1204'**. The first member **1202'** has a balanced centroidal axis “N1”, and first and second flanges **1208'** and **1218'**. The first flange **1208'** is angularly offset from the balanced centroidal axis N1' (i.e. it is asymmetric relative to the balanced centroidal axis N1') and the second flange **1218'** is also angularly offset from the nominal axis N1' (i.e. it is asymmetric relative to the balanced centroidal axis N1').

The flange of the joint members described above need not be circular, elliptical, or another symmetrical shape in plan view, and need not lie in a single plane. For example, FIGS. **41-43** illustrate a joint member **1302**. Its interior defines a

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nominal cup surface **1306**. The interior includes a cantilevered first flange **1308**, defined in part by an undercut groove **1312** formed in the first member **1302**. The first flange **1308** includes a protruding first contact rim **1316**. The first contact rim **1316** may have a straight, curved, or toroidal cross-sectional shape. The interior also includes a cantilevered second flange **1318** which is defined in part by an undercut groove **1322** formed in the first member **1302**. The second flange **1318** includes a protruding second contact rim **1324**. The second contact rim **1324** may have a straight, curved, or toroidal cross-sectional shape.

The first flange **1308** (and therefore the first contact rim **1316**) have a "saddle" shape. In this particular example it has a racetrack shape in plan view, and the portions at the ends of the major axis of the racetrack shape are elevated (in the z-direction) relative to the remainder of the shape. The first contact rim **1316** is shaped so as to define a contact band in which some or all points on its surface lie on a sphere (or otherwise match the shape of the mating convex joint member described above). The second flange **1318** could have a similar saddle shape as well.

The prosthetic joints described herein may include one or more flanges with an open perimeter. For example, FIGS. **44** and **45** illustrate another alternative prosthetic joint **1400** comprising first and second members **1402** and **1404**. The illustrated prosthetic joint **1400** is generally similar in construction and function to the prosthetic joint **1000** described above, and one or both of the members **1402** and **1404** may be bone-implantable as described above.

A balanced centroidal axis "N2", may be considered to pass through the first member **1402**. This axis N2 is defined in the same manner as the balanced centroidal axis "N1" described above. The first member **1402** is constructed from a rigid material and may generally be thought of as a "cup", as described above. Its interior defines a nominal cup surface **1406**. The interior includes a cantilevered first flange **1408**, defined in part by an undercut groove **1412** formed in the first member **1402**. A ramped surface **1414** forms a transition from the groove **1412** to the nominal cup surface **1406**. The first flange **1408** includes a protruding first contact rim **1416**. The first contact rim **1416** may have a straight, curved, or toroidal cross-sectional shape.

The first flange **1408** has an angular offset relative to the balanced centroidal axis N2, in other words it is asymmetric relative to the balanced centroidal axis N2. The interior also includes a cantilevered second flange **1418** which is defined in part by an undercut groove **1422** formed in the first member **1402**. The second flange **1418** includes a protruding second contact rim **1424**. The second contact rim **1424** may have a straight, curved, or toroidal cross-sectional shape.

In the example shown in FIGS. **44** and **45**, the second flange **1418** is also angularly offset from the balanced centroidal axis N2, i.e. it is asymmetric relative to the balanced centroidal axis.

The interior also includes a cantilevered third flange **1429** which is defined in part by an undercut groove **1430** formed in the first member **1402**. The third flange **1418** includes a protruding third contact rim **1432**. The third contact rim **1432** may have a straight, curved, or toroidal cross-sectional shape. As best seen in FIG. **45**, the third flange **1429** has an open perimeter, circumscribing less than 360 degrees. The distal ends of the third flange **1429** may be feathered away from the nominal cup surface, for example either by tapering the third flange's thickness or by tilting the distal ends outward relative to the remainder of the flange, so as not to contact the contact surface **1428** of the second member **1404**.

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The third flange **1429** could be symmetric or asymmetric relative to the balanced centroidal axis N2.

The second member **1402** is also made from a rigid material and has a wear-resistant, convex contact surface **1428**. The first, second, and third contact rims **1416**, **1424**, and **1432**, bear directly against the contact surface **1428** so as to transfer axial and lateral loads from one member to the other while allowing pivoting motion between the two members **1402** and **1404**.

Nominally the first, second, and third contact rims **1416**, **1424**, and **1432** define three separate "ring" or "band" contact interfaces with the contact surface **1428** of the second member **1404**. The flanges **1408**, **1418**, and **1429** (and thus the contact rims **1216**, **1224**, and **1432**) of the first member **1402** are conformable to the contact surface **1428** when the joint **1400** is placed under load. The flanges **1408**, **1418**, and **1429** can conform to the imperfect contact surface **1428** and deflect in an irregular shape, in the manner described above for the joint **1000**.

The facing surfaces of either or both of the first and second members **1402** and **1404** may include a face layer of a known coating such as titanium nitride, chrome plating, carbon thin films, and/or diamond-like carbon coatings, and/or a another substantially thicker wear-resistant material such as ultra-high molecular weight (UHMW) polyethylene. This face layer is used to impart wear resistance, as described above.

Any of the flanges may have an open perimeter. For example, FIGS. **46** and **47** illustrate a prosthetic joint **1400'** similar in construction to the prosthetic joint **1400**, including first and second members **1402'** and **1404'**. The first member **1402'** includes cantilevered first, second, and third flanges **1408'**, **1418'**, and **1429'**. In this example the first and third flanges **1408'** and **1429'** have a closed perimeter, and the second flange **1418'** has an open perimeter, circumscribing less than 360 degrees. Any or all of the flanges **1408'**, **1418'**, and **1429'** may be angularly offset from (i.e. asymmetric relative to) a balanced centroidal axis "N3" of the first member **1402'**, as described above. The construction and function of the joint **1400'** is otherwise identical to the joint **1400**. As described above for the flange **1429**, the distal ends of any flange having an open perimeter may be feathered away from the nominal cup surface, for example either by tapering the flange's thickness or by tilting the distal ends outward relative to the remainder of the flange, so as not to contact the contact surface of opposing member.

FIGS. **48** and **49** illustrate a prosthetic joint member **1502**, which may be used with any of the convex joint members described above.

The member **1502** is constructed from a rigid material and generally has a concave "cup" shape as described above. It may also be bone-implantable as described above. Its interior defines a nominal cup surface **1506**. The interior includes a cantilevered flange **1508**, defined in part by an undercut groove **1512** formed in the first member **1502**. A ramped surface **1514** forms a transition from the groove **1512** to the nominal cup surface **1506**. The flange **1508** includes a protruding first contact rim **1516**. The first contact rim **1516** may have a straight, curved, or toroidal cross-sectional shape. The flange **1508** may include an angular offset relative to a balanced centroidal of the joint member **1502**, as described above.

A peripheral groove **1520** is formed in the nominal cup surface **1506**. In the example shown in FIGS. **48** and **49**, it has a "T"-shaped cross-section. A contact ring **1522** is received in the groove **1520**. A part of the contact ring **1522** protrudes from the nominal cup surface **1506** and defines a second contact rim **1524**. In the illustrated example, the contact ring

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**1522** has “hat section” cross-sectional shape, with distal flanges that are received in the T-shaped groove **1520**.

The contact ring **1522** is made of a rigid material and has a wear-resistant surface, as those terms are described above. It is sized and shaped to achieve controlled elastic deflection, and to be conformable in the manner of the flanges described above. Its construction is thin enough to permit bending under working loads, but not so thin as to allow material yield or fatigue cracking. Deflection of the contact ring **1522** is opposed by the elasticity of the contact ring **1522** in bending, as well as the hoop stresses therein. To achieve long life, the contact ring **1522** is sized so that stresses therein will be less than the endurance limit of the material.

Various cross-sectional shapes may be used for the contact ring. For example, FIG. **50** illustrates a contact ring **1522'** with a “Z” shape and a doubled-over retention flange **1523**. FIG. **51** illustrates a contact ring **1522''** with a circular cross-section. The grooves **1520'** and **1520''** are modified to accommodate their respective contact rings **1522'** and **1522''**.

Nominally the first and second contact rims **1516** and **1524** define two separate “ring” or “band” contact interfaces with the contact surface of the opposed convex member (not shown). The contact rims **1516** and **1524** are conformable to an opposed contact surface when the joint is placed under load.

Any of the joint members described above may include holes or apertures formed therein to reduce their weight, or to facilitate manufacture or installation. For example, FIG. **52** illustrates a cup joint member **1602** with first and second flanges **1608** and **1618**, and an aperture **1610** formed near the apex of the cup shape.

While the joint members have been illustrated above with monolithic construction, any of the joint members may be made from one or more components built up to form the whole. For example, FIG. **53** illustrates a joint member **1702** which is a cup having a first flange **1708** and a second flange **1718** as described above. The joint member **1702** is made up from an annular first section **1710** and a cap-like second section **1711** which fit together to form the completed cup shape. The two sections **1710** and **1711** are fixed to each other, for example by a mechanical (e.g. interference) fit, an adhesive, welding or other thermal bonding method, or fasteners.

FIG. **54** illustrates a prosthetic joint member **1802**, which may be used with any of the convex joint members described above.

The member **1802** is constructed from a rigid material and generally has a concave “cup” shape as described above. It may also be bone-implantable as described above. It is made up from a shell **1804** with an interior surface **1806**, and a liner **1808** which fits conformally against the interior surface **1806**. The liner **1808** may be fixed or moveable relative to the shell **1804**. An interior of the liner **1808** defines a nominal cup surface **1810**. The liner **1808** includes a first peripheral ring **1812**, defined as a generally “U”-shape formed in the liner **1808**. The first peripheral ring **1812** includes a protruding first contact rim **1816**. The first contact rim **1816** may have a straight, curved, or toroidal cross-sectional shape. The first peripheral ring **1812** may include an angular offset or asymmetric positioning relative to a balanced centroidal axis “N4” of the joint member **1802**, as that concept is described above.

The liner **1808** also includes a second peripheral ring **1818**, defined as a generally “U”-shape formed in the liner **1808**. The second peripheral ring **1818** includes a protruding second contact rim **1820**. The second contact rim **1820** may have a straight, curved, or toroidal cross-sectional shape. The second peripheral ring **1818** may include an angular offset relative to

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a balanced centroidal axis “N4” of the joint member **1802**, as that concept is described above.

The liner **1808** is made of a rigid material and has a wear-resistant surface, as those terms are described above. The first and second peripheral rings **1812** and **1818** are sized and shaped to achieve controlled elastic deflection, and to be conformable in the manner of the flanges described above. Their construction is thin enough to permit bending under working loads, but not so thin as to allow material yield or fatigue cracking. Deflection of the contact rings **1812** and **1818** are opposed by the elasticity of the rings in bending, as well as the hoop stresses therein. To achieve long life, the contact rings **1812** and **1818** are sized so that stresses therein will be less than the endurance limit of the material.

Nominally the first and second contact rims **1816** and **1820** define two separate “ring” or “band” contact interfaces with the contact surface of the opposed convex member (not shown). The contact rims **1816** and **1820** are conformable to the opposed contact surface when the joint is placed under load.

FIGS. **55-58** illustrate an alternative prosthetic joint member **1902**. The illustrated prosthetic joint member **1902** is generally similar in construction and function to the prosthetic joint member **1202** described above, and is intended to be used with a complementary joint member having a convex or ball-like structure, such as the joint member **1204**, in order to constitute a complete prosthetic joint.

For purposes of explanation and illustration the joint member **1902** will be described relative to a “balanced centroidal axis”, labeled “N5” in FIG. **55**, passing through it. The meaning of the term “balanced centroidal axis” is described above.

The joint member **1902** includes a cup **1904** and an insert **1906**. The cup **1904** has interior and exterior surfaces **1908** and **1910**, respectively. The exterior surface **1910** may be configured to be bone-implantable as described above. A peripheral rim **1912** extends around the open edge of the cup **1904**. The peripheral rim **1912** includes a first indexing feature **1914** formed therein. In the particular example illustrated, the first indexing feature is a plurality of grooves or slots.

The insert **1906** is constructed from a rigid material and has a generally hemispherical shape. Its interior defines a nominal surface **1916**. The interior is configured similar to that of the joint member **1202** described above and includes a cantilevered first flange **1918**, defined in part by an undercut groove **1920** formed in the nominal surface **1916**. The first flange **1918** has an angular offset relative to the balanced centroidal axis N5, and the first flange **1918** includes a protruding first contact rim **1922**. The first contact rim **1922** may have a straight, curved, or toroidal cross-sectional shape.

The interior also includes a cantilevered second flange **1924** which is defined in part by an undercut groove **1926** formed in the nominal surface **1916**. The second flange **1924** includes a protruding second contact rim **1928**. The second contact rim **1928** may have a straight, curved, or toroidal cross-sectional shape. Depending on the specific application, the second flange **1924** may have an angular offset like the first flange **1918**. The flanges **1918** and **1924** (and thus the contact rims **1922** and **1928**) of the joint member **1902** are conformable to the contact surface of an opposed convex joint member when the joint is placed under load. The flanges **1918** and **1924** can conform to the imperfect contact surface and deflect in an irregular shape, in the manner described above for the joint **1000** described above. Contact between the contact rims and the contact surface of an opposed convex joint

member permits transfer of axial and lateral loads from one member to the other while allowing pivoting motion between the two members.

A peripheral rim **1930** extends around the open edge of the insert **1906**. The peripheral rim **1930** includes a second indexing feature **1932** formed therein. In the particular example illustrated, the second indexing feature **1932** is a plurality of tabs or ribs.

When the insert **1906** is assembled to the cup **1904**, the first and second indexing features **1914** and **1932** engage each other and prevent relative rotation of the cup **1904** and the insert **1906** (i.e. retaining the insert **1906** in a fixed angular orientation relative to the cup **1904**). The construction of the indexing features may be modified or inverted as needed to suit a particular application. For example, the peripheral rim **1930** of the insert **1906** may include slots or grooves while the peripheral rim **1912** of the cup **1904** could have tabs or ribs. The indexing features **1914** or **1932** may have a tapered or wedge shape to ensure that any clearance present between the two is taken up upon assembly of the cup **1904** to the insert **1906**.

The joint member **1902** may be implanted by first placing the cup **1904** into a prepared bone surface (not shown), then selecting a specific orientation for the insert **1906**. The insert **1906** is then placed into the cup **1904** in the selected orientation. The first and second indexing features **1914** and **1932** ensure that this orientation is maintained. Typically the cup **1904** would be placed using bone cement or a fastening process which must be completed in one step, or it would be difficult and/or undesirable to remove and replace the cup **1904**. Because the cup **1904** and the insert **1906** are separate from each other, there is no need to maintain any particular rotational alignment of the cup **1904** about the axis **N5** as it is placed, yet the insert **1906** can be clocked relative to the cup **1904** to place the flanges **1918** and **1924** in a precise orientation when finally assembled.

FIG. **59** illustrates an alternative prosthetic joint member **2002**. It is generally similar in construction and function to the prosthetic joint member **1902** described above, and includes a cup **2004** and an insert **2006**. The cup **2004** has interior and exterior surfaces **2008** and **2010**, respectively, and the exterior surface **2010** may be configured to be bone-implantable as described above. A first indexing feature **2014** is formed in the interior of the cup **2004** adjacent the open edge of the cup **2004**. In the particular example illustrated, the first indexing feature **2014** is a plurality of axially-aligned grooves or slots.

The insert **2006** is constructed from a rigid material and has a generally hemispherical shape. Its interior defines a nominal surface **2016**. The interior is configured similar to that of the joint member **1202** described above and includes a cantilevered first flange **2018**, defined in part by an undercut groove (not visible) formed in the nominal surface **2016**. The first flange **2018** has an angular offset relative to a balanced centroidal axis **N6** of the insert **2006**, and the first flange **2018** includes a protruding first contact rim **2022**. The first contact rim **2022** may have a straight, curved, or toroidal cross-sectional shape.

The interior also includes a cantilevered second flange **2024** which is defined in part by an undercut groove formed in the nominal surface **2016**. The second flange **2024** includes a protruding second contact rim **2028**. The second contact rim **2028** may have a straight, curved, or toroidal cross-sectional shape. Depending on the specific application, the second flange **2024** may have an angular offset like the first flange **2018**. The flanges **2018** and **2024** (and thus the contact rims **2022** and **2028**) of the joint member **2002** are

conformable to the contact surface of an opposed convex joint member when the joint is placed under load. The flanges **2018** and **2024** can conform to the imperfect contact surface and deflect in an irregular shape, in the manner described above for the joint **1000** described above.

A second indexing feature **2032** is formed on the exterior of the insert **2006**, adjacent its open edge. In the particular example illustrated, the second indexing feature **2032** is a plurality of axially-aligned ribs protruding radially outward. The ribs have a cross-sectional shape which is complementary to the grooves of the first indexing feature **2014**.

The joint member **2002** may be implanted using the process described above for the joint member **1902**. When the insert **2006** is assembled to the cup **2004**, the first and second indexing features **2014** and **2032** engage each other and prevent relative rotation of the cup **2004** and the insert **2006**. The construction of the indexing features may be modified or inverted as needed to suit a particular application. For example, the insert **2006** may include slots or grooves while the cup **2004** could have tabs or ribs. The indexing features **2014** or **2032** may have a tapered or wedge shape to ensure that any clearance present between the two is taken up upon assembly of the cup **2004** to the insert **2006**.

FIGS. **60-62** illustrate an alternative prosthetic joint member **3002**. The illustrated prosthetic joint member **3002** is generally similar in construction and function to the prosthetic joint member **1202** described above, and is intended to be used with a complementary joint member having a convex or ball-like structure, such as the joint member **1204**, in order to constitute a complete prosthetic joint.

For purposes of explanation and illustration the joint member **3002** will be described relative to a "balanced centroidal axis", labeled "N7" in FIG. **60**, passing through it. The meaning of the term "balanced centroidal axis" is described above.

The joint member **3002** includes a cup **3004** and an insert **3006**. The cup **3004** has interior and exterior surfaces **3008** and **3010**, respectively. The exterior surface **3010** may be configured to be bone-implantable as described above. The interior surface **3008** has an annular retention groove **3012** formed therein. The retention groove includes a side wall **3013** and an end wall **3015**. The end wall **3015** may be angled, as shown in FIG. **61**, so that its inboard end is closer to the open end of the cup **3004** than its outboard end.

The insert **3006** is constructed from a rigid material and has a generally hemispherical shape. Its interior defines a nominal surface **3016**. The interior is configured similar to that of the joint member **1202** described above and includes a cantilevered first flange **3018**, defined in part by an undercut groove **3020** formed in the nominal surface **3016**. The first flange **3018** has an angular offset relative to the balanced centroidal axis **N7**, and the first flange **3018** includes a protruding first contact rim **3022**. The first contact rim **3022** may have a straight, curved, or toroidal cross-sectional shape.

The interior also includes a cantilevered second flange **3024** which is defined in part by an undercut groove **3026** formed in the nominal surface **3016**. The second flange **3024** includes a protruding second contact rim **3028**. The second contact rim **3028** may have a straight, curved, or toroidal cross-sectional shape. Depending on the specific application, the second flange **3024** may have an angular offset like the first flange **3018**. The flanges **3018** and **3024** (and thus the contact rims **3022** and **3028**) of the joint member **3002** are conformable to the contact surface of an opposed convex joint member when the joint is placed under load. The flanges **3018** and **3024** can conform to the imperfect contact surface and deflect in an irregular shape, in the manner described above for the joint **1000** described above.



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As best seen in FIG. 62, a plurality of retention tabs 3030 extend outward from an outer surface 3032 of the insert 3006. In the illustrated example the retention tabs 3030 are integrally formed with the insert 3006, but they could be formed separately and then attached to the insert 3006. The retention tabs 3030 are cantilevered spring members and are sized and shaped to fit into the retention groove 3012 of the cup 3004. As shown the retention tabs 3030 are arrayed evenly around the periphery of the insert 3006. The specific configuration of the retention tabs 3030 may be altered to suit a particular application, for example the angular width, length, thickness, and number of tabs may be altered as needed.

Referring to FIGS. 60 and 61, when the insert 3006 is assembled to the cup 3004, the retention tabs 3030 will be deflected inward. When the insert is fully seated the retention tabs 3030 will spring outward into the retention groove 3012, holding the insert 3006 securely engaged with the cup 3004. The retention tabs 3030 may be configured to have a “self-locking” function, such that their engagement with the retention groove 3012 is assured even if the insert 3006 is displaced further into the cup 3004. For example, as shown in FIG. 61, each retention tab 3030 includes an end face 3031 which is roughly parallel to the angled end wall 3015 of the retention groove 3012. Initial contact with the end wall 3015 limits the outward motion of the retention tabs 3030 before they contact the side wall 3013. It can be seen that if the insert 3006 is advanced further into the cup 3006 the retention tabs 3030 will spring outward an additional amount allowing the end face 3031 to advance further along the end wall 3015, but always maintaining contact.

FIGS. 63 and 64 illustrate an alternative prosthetic joint member 4002. The illustrated prosthetic joint member 4002 is generally similar in construction and function to the prosthetic joint member 3002 described above, and is intended to be used with a complementary joint member having a convex or ball-like structure, such as the joint member 1204, in order to constitute a complete prosthetic joint.

For purposes of explanation and illustration the joint member 4002 will be described relative to a “balanced centroidal axis”, labeled “N8” in FIG. 63, passing through it. The meaning of the term “balanced centroidal axis” is described above.

The joint member 4002 includes a cup 4004 and an insert 4006. The cup 4004 has interior and exterior surfaces 4008 and 4010, respectively. The exterior surface 4010 may be configured to be bone-implantable as described above. The interior surface 4008 has a first detent element 4012 formed therein, in this particular example a concave groove. The first detent element 4012 could be a continuous annular groove, or it could comprise an annular array of individual recesses.

The insert 4006 is constructed from a rigid material and has a generally hemispherical shape. Its interior defines a nominal surface 4016. The interior is configured similar to that of the joint member 3002 described above and includes a cantilevered first flange 4018, defined in part by an undercut groove 4020 formed in the nominal surface 4016. The first flange 4018 has an angular offset relative to the balanced centroidal axis N8, and the first flange 4018 includes a protruding first contact rim 4022. The first contact rim 4022 may have a straight, curved, or toroidal cross-sectional shape.

The interior also includes a cantilevered second flange 4024 which is defined in part by an undercut groove 4026 formed in the nominal surface 4016. The second flange 4024 includes a protruding second contact rim 4028. The second contact rim 4028 may have a straight, curved, or toroidal cross-sectional shape. Depending on the specific application, the second flange 4024 may have an angular offset like the first flange 4018. The flanges 4018 and 4024 (and thus the

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contact rims 4022 and 4028) of the joint member 4002 are conformable to the contact surface of an opposed convex joint member when the joint is placed under load. The flanges 4018 and 4024 can conform to the imperfect contact surface and deflect in an irregular shape, in the manner described above for the joint 1000 described above.

A second detent feature 4030, in this particular example a convex rib, is formed on an outer surface 4032 of the insert 3006. The second detent feature 4030 could be a continuous protruding annular rib, or it could comprise an annular array of individual, dome-like protrusions. The second detent element 4030 is sized and shaped to fit into the first detent elements 4012 of the cup 4004. Cooperatively, the detent elements 4012 and 4030 function as a “detent” in the sense that, when the detent elements 4012 and 4030 are engaged with each other, they prevent relative movement of the cup 4004 and the insert 4006. The specific configuration of the detent elements 4012 and 4030 may be altered to suit a particular application, for example the shape, size, and number of the detent elements may be altered as needed. Furthermore the concave/convex relationship between the detent elements 4012 and 4030 may be reversed.

When the insert 4006 is assembled to the cup 4004, the second detent elements 4030 will engage the first detent element 4012, holding the insert 4006 securely engaged with the cup 4004. In cases where the first and second detent elements 4012 and 4030 each comprise a plurality of discrete members, the cooperating detent elements would also serve to positively index the relative angular orientation of the cup 4004 and the insert 4006, in the manner described above.

FIG. 65 illustrates an alternative prosthetic joint member 5002. The illustrated prosthetic joint member 5002 is generally similar in construction and function to the prosthetic joint member 1202 described above, and is intended to be used with a complementary joint member having a convex or ball-like structure, such as the joint member 1204, in order to constitute a complete prosthetic joint.

For purposes of explanation and illustration the joint member 5002 will be described relative to a “balanced centroidal axis”, labeled “N9” in FIG. 65, passing through it. The meaning of the term “balanced centroidal axis” is described above.

The joint member 5002 includes a cup 5004 and an insert 5006. The cup 5004 has interior and exterior surfaces 5008 and 5010, respectively. The exterior surface 5010 may be configured to be bone-implantable as described above.

The insert 5006 is constructed from a rigid material and has a generally hemispherical shape. Its interior defines a nominal surface 5016. The interior is configured similar to that of the joint member 1202 described above and includes a cantilevered first flange 5018, defined in part by an undercut groove 5020 formed in the nominal surface 5016. The first flange 5018 has an angular offset relative to the balanced centroidal axis N9, and the first flange 5018 includes a protruding first contact rim 5022. The first contact rim 5022 may have a straight, curved, or toroidal cross-sectional shape.

The interior also includes a cantilevered second flange 5024 which is defined in part by an undercut groove 5026 formed in the nominal surface 5016. The second flange 5024 includes a protruding second contact rim 5028. The second contact rim 5028 may have a straight, curved, or toroidal cross-sectional shape. Depending on the specific application, the second flange 5024 may have an angular offset like the first flange 5018. The flanges 5018 and 5024 (and thus the contact rims 5022 and 5028) of the joint member 5002 are conformable to the contact surface of an opposed convex joint member when the joint is placed under load. The flanges 5018 and 5024 can conform to the imperfect contact surface and



deflect in an irregular shape, in the manner described above for the joint **1000** described above.

A compliant spacer **5030** is disposed between the cup **5004** and the insert **5006**. The spacer **5030** is constructed from a material that is sufficiently “soft” to deform compliantly when the insert **5006** is installed in the cup **5004**. Nonlimiting examples of suitable materials for the spacer **5030** include polymers and elastomeric materials. The spacer **5030** is fixed relative to the insert **5006**. One function of the spacer **5030** is to compliantly support the insert **5006** inside the cup **5004**. It is possible that the cup **5004** can be implanted so that its interior surface **5008** is distorted from a nominal shape. Rigid installation of the insert **5006** directly against the cup **5004** could in turn cause excessive distortion of the insert **5006**. In such situations the compliant nature of the spacer **5006** allows the insert **5006** to remain in a nominal shape.

It is also possible for the spacer **5030** to provide overload protection to the joint member **5002**. Specifically, when the joint member **5002** is subjected to a load beyond the normal working range of the flanges **5018** and **5024**, the convex joint member will tend to “bottom out” against the insert **5006**, resulting in metal-to-metal contact with high local contact stresses. In such situations, the compliant nature of the spacer **5030** allows it to compress under loading and permit the insert **5006** to move towards the cup **5004**, relieving the high contact stresses. The spacer **5030** will return to its original shape and dimensions when the loading is removed.

FIGS. **66** and **67** illustrate another alternative prosthetic joint member **6002**. The illustrated prosthetic joint member **6002** is generally similar in construction and function to the prosthetic joint member **1202** described above, and is intended to be used with a complementary joint member having a convex or ball-like structure, such as the joint member **1204**, in order to constitute a complete prosthetic joint.

For purposes of explanation and illustration the joint member **6002** will be described relative to a “balanced centroidal axis”, labeled “N10” in FIG. **66**, passing through it. The meaning of the term “balanced centroidal axis” is described above.

The joint member **6002** includes a cup **6004** and an insert **6006**. The cup **6004** has interior and exterior surfaces **6008** and **6010**, respectively. The exterior surface **6010** may be configured to be bone-implantable as described above. First and second annular spacer grooves **6012** and **6014** are formed in the interior surface **6008**. Each spacer groove **6012** and **6014** has a generally “T”-shaped cross-sectional shape.

The insert **6006** is constructed from a rigid material and has a generally hemispherical shape. Its interior defines a nominal surface **6016**. The interior is configured similar to that of the joint member **1202** described above and includes a cantilevered first flange **6018**, defined in part by an undercut groove **6020** formed in the nominal surface **6016**. The first flange **6018** has an angular offset relative to the balanced centroidal axis N10, and the first flange **6018** includes a protruding first contact rim **6022**. The first contact rim **6022** may have a straight, curved, or toroidal cross-sectional shape.

The interior also includes a cantilevered second flange **6024** which is defined in part by an undercut groove **6026** formed in the nominal surface **6016**. The second flange **6024** includes a protruding second contact rim **6028**. The second contact rim **6028** may have a straight, curved, or toroidal cross-sectional shape. Depending on the specific application, the second flange **6024** may have an angular offset like the first flange **6018**. The flanges **6018** and **6024** (and thus the contact rims **6022** and **6028**) of the joint member **6002** are conformable to the contact surface of an opposed convex joint member when the joint is placed under load. The flanges **6018**

and **6024** can conform to the imperfect contact surface and deflect in an irregular shape, in the manner described above for the joint **1000** described above.

A resilient first spacer ring **6030** is disposed between the cup **6004** and the insert **6006**. The first spacer ring **6030** has a cross-sectional shape generally referred to as a “hat” section with laterally-extending flanges **6032**. The flanges **6032** are received in the T-shaped first spacer groove **6012**. A second spacer ring **6034** of identical configuration to the first spacer ring **6030** is received in the second spacer groove **6014**. The first and second spacer rings **6030** and **6034** are configured so as to resiliently (or elastically) deflect under loading and permit the insert **6006** to move towards the cup **6004**, then return to its original shape and dimensions when the loading is removed. Nonlimiting examples of suitable materials for the spacer rings **6030** include metal alloys, polymers and elastomeric materials.

FIGS. **68** and **69** depict a joint member **7002** having a cup **7004** and insert **7006**. The insert **7006** is of identical construction to the insert **6006** described above. The cup **7004** is identical in construction to the cup **6004** described above except for the configuration of the first and second spacer grooves **7012** and **7014**, both of which have plain rectangular cross-sectional shapes.

A resilient first spacer ring **7030** is disposed between the cup **7004** and the insert **7006**. The first spacer ring **7030** has a closed-loop cross-sectional shape (e.g. circular, oval, or elliptical). A second spacer ring **7034** of identical configuration to the first spacer ring **7030** is received in the second spacer groove **7014**. The first and second spacer rings **7030** and **7034** are configured so as to resiliently (or elastically) deflect under loading and permit the insert **7006** to move towards the cup **7004**, then return to its original shape and dimensions when the loading is removed. Nonlimiting examples of suitable materials for the spacer rings **7030** and **7034** include metal alloys, polymers and elastomeric materials.

FIG. **70** illustrates another alternative prosthetic joint member **8002**. The illustrated prosthetic joint member **8002** is generally similar in construction and function to the prosthetic joint member **1202** described above, and is intended to be used with a complementary joint member having a convex or ball-like structure, such as the joint member **1204**, in order to constitute a complete prosthetic joint.

For purposes of explanation and illustration the joint member **8002** will be described relative to a “balanced centroidal axis”, labeled “N11” in FIG. **70**, passing through it. The meaning of the term “balanced centroidal axis” is described above.

The joint member **8002** includes a cup **8004** and an insert **8006**. The cup **8004** has interior and exterior surfaces **8008** and **8010**, respectively. The exterior surface **8010** may be configured to be bone-implantable as described above. A peripheral rim **8012** extends around the open edge of the cup **8004**. The rim **8012** is shaped so as to define an annular, L-shaped interior corner or “step” **8014**.

The insert **8006** is constructed from a rigid material and has a generally hemispherical shape. Its interior defines a nominal surface **8016**. The interior is configured similar to that of the joint member **1202** described above and includes a cantilevered first flange **8018**, defined in part by an undercut groove **8020** formed in the nominal surface **8016**. The first flange **8018** has an angular offset relative to the balanced centroidal axis N11, and the first flange **8018** includes a protruding first contact rim **8022**. The first contact rim **8022** may have a straight, curved, or toroidal cross-sectional shape.

The interior also includes a cantilevered second flange **8024** which is defined in part by an undercut groove **8026**

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formed in the nominal surface **8016**. The second flange **8024** includes a protruding second contact rim **8028**. The second contact rim **8028** may have a straight, curved, or toroidal cross-sectional shape. Depending on the specific application, the second flange **8024** may have an angular offset like the first flange **8018**. The flanges **8018** and **8024** (and thus the contact rims **8022** and **8028**) of the joint member **8002** are conformable to the contact surface of an opposed convex joint member when the joint is placed under load. The flanges **8018** and **8024** can conform to the imperfect contact surface and deflect in an irregular shape, in the manner described above for the joint **1000** described above.

An annular lip **8030** extends radially outward from the open edge of the insert **8006**. The lip **8030** is received in the step **8014** of the cup **8004**. The dimensions of the cup **8004** and the insert **8006**, and the position of the step **8014** and the lip **8030** are selected such that, when the lip **8030** and the step **8014** are in contact, a definite clearance **8032** is present between the cup **8004** and the insert **8006**.

This clearance allows the insert **8006** to resiliently deflect under loading and move towards the cup **8004**, then return to its original shape and dimensions when the loading is removed. If desired, the clearance **8032** could be filled with a polymer or elastomeric material to tailor the deflection properties of the joint member **8002** and provide damping between the insert **8006** and the cup **8004**.

FIG. 71 depicts a joint member **8002'** having a cup **8004'** and insert **8006'**. These two components are of identical construction to the cup **8004** and insert **8006**, respectively, except for the configuration of the contact interface therebetween. Specifically, the step **8014'** of the cup **8004'** is angled rather than L-shaped in cross section. The lip **8030'** of the insert **8006'** has a surface with an angle matching the step **8014'**.

The features described above (that is, the indexing feature, the retention feature, or the resilient spacer) may be incorporated individually into a prosthetic joint member, or they may be applied to a joint member in any combination. For example, FIGS. 72 and 73 depict a prosthetic joint member **9002** similar in construction and function to the prosthetic joint member **2002** described above and having both indexing and retention features. The prosthetic joint member **9002** includes a cup **9004** and an insert **9006**. The cup **9004** includes first indexing features **9014** and the insert **9006** includes second indexing features **9032**. The cup **9002** also includes a retention groove **9012** and the insert **9006** includes retention tabs **9030**. As another example, FIG. 74 depicts a prosthetic joint member **10002** similar in construction and function to the prosthetic joint member **7002** described above and having both resilient spacers and an indexing feature. The prosthetic joint member **10002** includes a cup **10004** and an insert **10006**. The cup **10004** includes first indexing features **10014** and the insert **10006** includes second indexing features **10032**. The cup **10012** also includes spacer grooves **10012** that receive resilient spacer rings **10030**. It is also noted that, the flange of the joint members described above need not be circular, elliptical, or another symmetrical shape in plan view, and need not lie in a single plane. Plan view shapes such as oval, elliptical, and shapes formed from one or more splines is possible. One or more of the flanges may include an open perimeter. Furthermore, the sizing of the flanges and the contact rims relative to the expected loads applied thereto and considering fatigue considerations may be determined as described above for the similar flanges of the prosthetic joint **1000**.

As noted above, known coatings such as titanium nitride, chrome plating, carbon thin films, and/or diamond-like carbon coatings may be used to impart wear resistance or aug-

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ment the wear resistance of any of the contact surfaces and/or contact rims described above. To the same end, it may be desirable to surface treat either or both interfaces of any of the above-described implants or joints with a laser, shot peen, burnishing, or water shock process, to impart residual compressive stresses and reduce wear. The benefit could be as much from surface annealing and microstructure and microfracture elimination as smoothing itself.

The foregoing has described prosthetic joints with wear-resistant properties and conformal geometries. While specific embodiments of the present invention have been described, it will be apparent to those skilled in the art that various modifications thereto can be made without departing from the spirit and scope of the invention. Accordingly, the foregoing description of the preferred embodiment of the invention and the best mode for practicing the invention are provided for the purpose of illustration only and not for the purpose of limitation.

What is claimed is:

1. A prosthetic joint member comprising:

a concave cup with an outer surface that is bone-implantable, the cup including a first indexing feature;

a concave insert disposed inside the cup, the insert comprising a rigid material and including a concave interior defining a nominal surface, the interior including a cantilevered flange defined by an undercut in the rigid material, the flange defining a wear-resistant first contact surface which protrudes inward relative to the nominal surface and into the concave interior, the insert including a second indexing feature; and

wherein the first and second indexing features engage each other so as to retain the insert in a fixed angular orientation relative to the cup.

2. The prosthetic joint member of claim 1 wherein the flange is asymmetric relative to a balanced centroidal axis.

3. The prosthetic joint member of claim 1 wherein the first indexing feature comprises a ring of notches or grooves.

4. The prosthetic joint member of claim 3 wherein the second indexing feature comprises one or more ribs complementary to the notches or grooves.

5. The prosthetic joint member of claim 1, wherein:

the cup includes a first retention feature;

the insert includes a second retention feature; and

the first and second retention features engage each other to secure the cup and insert together.

6. The prosthetic joint member of claim 5, wherein the first retention feature is a groove and the second retention feature is a tab.

7. The prosthetic joint member of claim 6 wherein the tab and groove have cooperating shapes formed such that, after initial engagement of the tab with the groove, additional movement of the insert towards the cup will cause the tab to spring outward while remaining engaged with the groove.

8. The prosthetic joint member of claim 5, wherein the first and second retention feature comprise complementary detent elements.

9. The prosthetic joint member of claim 1 where the insert is resiliently suspended relative to the cup.

10. The prosthetic joint member of claim 1 wherein a compliant nonmetallic spacer is disposed between the cup and the insert.

11. The prosthetic joint member of claim 1 wherein the cup includes a step and the insert includes a lip which bears against the step, such that a clearance is present between the cup and the insert.

12. The prosthetic joint member of claim 1 wherein at least one elastically-deflectable spacer ring is disposed between the cup and the insert.

13. The prosthetic joint member of claim 12 wherein the spacer ring is received in a groove in the cup. 5

14. A prosthetic joint including the joint member of claim 1 and a convex member comprising a rigid material with a wear-resistant, convex contact surface received in the insert, where the first contact surface bears directly against the convex contact surface of the convex member, so as to transfer 10 axial and lateral loads between the joint member and the convex member, while allowing pivoting motion between the joint member and the convex member.

15. The prosthetic joint of claim 14, where the contact surfaces are ceramic, metallic, or a combination thereof. 15

16. The prosthetic joint of claim 14, where the flange is sized so as to permit elastic deflection of the flange while limiting stresses in the flange to less than the endurance limit of the material, when a predetermined external load is applied to the joint. 20

17. The prosthetic joint member of claim 1 wherein the flange has a plan view shape which is noncircular.

18. The prosthetic joint member of claim 1 wherein the flange has an open perimeter.

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